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and Without Breast Cancer and in Response to a Dietary

Intervention

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Phase I Induction and Estrogen Metabolism in Women With and Without Breast Cancer and in Response to a Dietary Intervention

Annual Report: Year 1

Introduction

Work by our group and others provide the scientific basis of this study. Cross-national studies of breast cancer rates and studies of migrants indicate that environmental factors are responsible for large population-level differences in breast cancer rates and rates of change over time. In a study of 46 countries, we found that over 90% of breast cancer mortality could be accounted for mainly by dietary factors. On a per-calorie basis, the strongest effect in the data was the protective effect of cabbage. There is some evidence that vegetables in the Brassica genus, like cabbage and broccoli, modify estrogen metabolism by causing 17β- Estradiol (E2) to be metabolized to 2-hydroxyestrone (2HE) rather than 16α-hydroxyestrone (16HE). Relative to 2HE, 16HE appears more likely to cause cancer and breast cancer patients have a lower ratio of these metabolites than do disease-free controls. It has further been shown that the P450 enzyme CYP1B1 is present in tumor but not normal breast tissue. The indole glucosinolates (IGSL), which are contained in high concentrations in Brassica vegetables, induce a number of protein products that can shift E2 metabolism away from 16HE and towards 2HE. AhR activation also induces immune system factors such as interleukin-1β (IL-1β) and other proteins, such as plasminogen activator inhibitor-2 (PAI-2), a protease inhibitor that has been associated with inhibition of tumor invasiveness (metastasis).

Specific Aims

The two objectives of this proposal are to evaluate the products of AhR activation against the risk of breast cancer, and to investigate the ability of Brassica vegetables to reduce breast cancer risk. Women will be recruited from among those undergoing a diagnostic biopsy at SCCC following a suspicious mammogram. The plan continues to be to enroll 30 postmenopausal women with breast cancer and 60 age-matched women found to be disease free, half of whom will be deemed to be at low risk according to the Gail/Benichou model (<7% risk in the next 10 years) and half of whom will be at higher risk (>10% risk). The first study, conducted at the time the women enter the study, will compare the 30 breast cancer patients and the 30 high-risk and 30 low-risk healthy women on: 1) AhR activation and its various protein products relevant to cancer including CYP1B1, PAI-2, and IL-1B; and 2) levels of relevant estrogens, E2, 2HE, and 16HE. The second study will examine the effect of an intensive Brassica-rich diet intervention on AhR activation, its protein products, and estrogen metabolites in these 90 women. Measurement of all study parameters will be made at times corresponding to the baseline period and post-intervention. Blood and fasting morning urine samples will be collected for measurement of the estrogens, and levels of PAI-2 and IL-1\u00ed. Adipose

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tissue for assay of CYP1B1 will be collected from routine open biopsy at the time of recruitment and from a fine needle biopsy of the contralateral breast at follow-up. Diet will be assessed by use of validated diet assessment instruments. Compliance also will be assessed by levels of isothiocyanates and dithiocarbamates in urines. Statistical analyses of the data will consist of t-tests and analysis of variance of mean levels of the parameters specified in the three groups at baseline. T-tests of change and regression analyses (e.g., repeat measures ANOVA) will focus both change and relative change in the intervention trial. Post hoc analyses will examine the effect of the indole carbinols by fitting the data as continuous, which takes into account varying levels of compliance.

The primary hypotheses are to:

- 1. examine differences in AhR and its protein products, including CYP1B1, PAI-2, and IL-1β, and estrogen metabolites at baseline in three subsets of women undergoing diagnostic open breast biopsy at SCCC;
- 2. determine if we can alter levels of these products and estrogen metabolites through intensive dietary intervention on Brassica vegetable intake; and
- 3. relate these products, especially CYP1B1, to the estrogen metabolites both cross-sectionally and longitudinally.

Work Accomplished

Work needed to accomplish this proposal has been performed at multiple levels. The study site for this project has been successfully transferred from the University of Massachusetts (UMass) to the University of South Carolina (USC). Two large hospitals that form Palmetto Health Alliance (PHA) will serve as the participant recruitment source. These hospitals treat about 30% more breast cancer patients compared to UMass, greatly facilitating the recruitment of participants into this study. It is further necessary to note the unexpected delay in receiving full IRB approval. The Funding Agency (DAMD) required specific language inserted into the consent form, language that was unacceptable to the local institutional review board. New language had to be crafted which was acceptable to both parties. This legal review process was beyond our control as investigators. However now all human use-related materials have been approved by the DAMD, the PHA, and the University of South Carolina (as of 29 November 2000) and we are pleased that we are able to recruit human subjects. Because of problems with human subject approvals and modifying procedures, the run-in phase lasted through the entire first year of the study period. Therefore, the timing for all phases is pushed back by 6 months. This in no way affects the actual task listing. In addition, with relatively small sample size and a larger population of potentially eligible patients, recruitment will proceed quickly. Therefore, there are no major implications for extending the ending time of the tasks (other than Task 1).

Task 1: Run-in Phase, Months 1-12:

a. Inventory and finalize all assessment instruments and data collection protocols.

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Assessment instruments have been inventoried and are available. Final versions of all assessment instruments have been produced, as stipulated in the protocol. Copies of these instruments are included in the appendix.

Below is a list of instruments being utilized.

<u>Baseline questionnaire</u> Measures include: Background and Demographic Data: age; sex; marital status; education; number of children; number and dates of pregnancies; breast feeding history: (months for each child); and menopausal status (including surgical menopause). Personal Health History: present medical/psychiatric history and treatment (including history of exposure to estrogens, oral contraceptives, unusual menstrual problems). Family Health History: history of breast cancer; history of other cancers. General Self Care: sleep; exercise frequency; and smoking status.

Besides data collected on the baseline instrument we also administered these other questionnaires:

- Marlowe-Crowe Social Desirability (MCSD) scale (Personal Reaction Inventory)
- Social Approval Scale
- 3-day diet diary
- Vegetable and Fruit Questionnaire
- Monitoring questionnaire
- Intervention Course Book, which includes intervention descriptions, food preparation methods, a cook book, telephone numbers of study personnel, and a brief description of the purposes of the study

New data collection protocols have been developed to fully utilize all resources under development at USC. We will mail an introductory letter and consent form to potential participants. We will follow-up this letter with a telephone call, and answer any questions regarding the study. A meeting will be scheduled at the study center located within the South Carolina Cancer Center (SCCC). The SCCC facility includes an interview room, sample processing lab, and calibrated scales and measurement instruments. At the meeting, participants will have the opportunity to ask additional questions regarding the consent form. After obtaining consent, we will obtain a urine sample, blood sample, buccal cells, body size measurements, and participant's will complete the baseline questionnaire. Follow-up measurements will be collected using a similar mechanism. Additionally, near the end of the intervention a clinic appointment will be scheduled for collection of breast biopsy material.

b. Review baseline questionnaires for completeness and for content validity.

All instrument materials have been thoroughly reviewed.

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c. Revise baseline questionnaire to assess demographic, health history, and family health history, as necessary.

The Baseline Questionnaire has been expanded to include a more complete description of each participant's health history and demographic status. This expansion followed the move to USC, and the greater population diversity in SC as compared to Massachusetts. The questionnaire has been pilot tested, and appears to be sufficiently clear and complete.

d. Hire and train the Research Assistant.

Several personnel have been hired in order to complete this, and other, research projects. Dr. Jay Fowke has joined the USC faculty as a Research Assistant Professor. Dr. Fowke is acting as Project Coordinator, and will be largely responsible for the day-to-day operations of the project. Mary Margaret Hoy has been hired as a full-time data manager. Ms. Hoy has primary responsibility for developing the tracking databases necessary for ensuring complete recruitment and data collection, and she will be responsible for questionnaire maintenance, questionnaire development, and data entry. Yasmin Khan is a Masters student in the Department of Epidemiology, and Ms. Mary Modayil will be the doctoral graduate research assistant on this project. Her primary responsibility will be to assist Ms. Hoy and Dr. Fowke in identifying potentially eligible participants, mailings, and data management.

e. Develop the study data management systems, using a combination of Lotus Notes, Microsoft Excel, and EpiInfo.

Ms. Hoy has developed an improved data management system using optical scanning technology and the Teleform software package. Lotus Notes will not be used in this study as we are moving to more universally recognized solutions. Questionnaires will be optically scanned, removing operator error associated with keypunching data, and greatly speeding the data entry process. Optically scanned data are directly transferred to a SAS dataset for analysis, thus eliminating most of the need for EpiInfo.

f. Develop the tracking database in Lotus Notes based on our experience with other intervention studies in the Department of Epidemiology and Biostatistics.

We are in the process of developing an extensive database system, which links directly with the clinical hospital patient bases and other ongoing cancer studies. Once completed, this data management system will be able to rapidly identify potentially eligible women receiving care at one of the cancer centers. This information will be converted to the study-specific tracking system, used for maintaining records of recruitment, participant status, and data collection. The first phase of this extensive data management system will be tested within the

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month (January to February 2001), and subsequent tracking systems will be tested and completed.

g. Train staff in all data-related and clinic-based procedures.

We have trained staff to conduct all data-related procedures. Dr. Fowke has experience is data management and analysis, and together with Dr. Hebert, will be responsible for the overall data management and statistical analysis. Ms. Hoy, the data manager, has received formal training in the Teleform software package and extensive experience using the SAS software package. The graduate research assistants have been trained in the application of Teleform and they are developing the skills necessary to perform many routine SAS data management operations. Dr. Fowke has trained Ms. Khan to collect body size measurements using standard and systematic protocols. Additionally, Dr. Fowke has trained the assistant in urine and buccal cell collection, sample preparation, and storage protocols. The biopsy collection protocol will be conducted by one of the members of the Radiology Department with the PHA hospital network.

h. Develop and finalize all laboratory procedures to be used in the trial.

The majority of laboratory procedures will be conducted by Dr. Mark Davis at USC. With the exception of the CYP1B1 assay, all necessary laboratory protocols are commercially available as kits. Members of Dr. Davis' lab have extensive experience in forming radioimmunoassays and enzyme immunoassays as required through use of these kits. The CYP1B1 assay will be conducted by Dr. Carson within the Department of Exercise Science

i. Finalize all biological sample collection and storage procedures to be used in the study.

All biological sample collection and storage procedures have been drafted. The collection protocols for urine, blood, and buccal cells are finalized. The biopsy collection protocol is currently being revised, due to new published findings suggesting better methods to detect CYP1B1 in breast tissue. We are developing this new collection and assay protocol in consultation with leading experts in this field (William Greenlee, Kathleen Shriverick), and we will have a finalized collection protocol and assay befor the start of recruitment.

j. Establish recruitment procedures for women entering the study, including pre-screen for certain criteria such as menopausal status.

Recruitment procedures have been established. We will identify women seeking a screening mammogram at one of the clinical centers within the PHA. We have developed the data management system such that we will be able to identify

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women who receive a negative screening (healthy) and women who eventually are diagnosed with breast cancer.

k. Finalize the intervention protocol.

We have developed the intervention protocol, based on our experiences with past dietary interventions. An intervention syllabus has been generated, listing specific content and topics for each class. Intervention materials have been generated, including a course booklet, 3-day diet diaries, a brief vegetable questionnaire, a brief monitoring questionnaire designed to measure adverse reactions or changes in health-related behaviors, and a recipe book. Dietary goals have been set. Rapid conversion of self-reported compliance levels will allow participants to monitor compliance relative to peers. We have identified several dieticians in Columbia who are sufficiently skilled to lead the intervention, and we are confident in our ability to hire such an intervention leader at the appropriate time.

Task 2: Recruitment, Months 12-24:

a. Identify women who could be eligible for the study from among those visiting the Breast Clinic at Richland Memorial Hospital for the purpose of an open biopsy as a part of a diagnostic work up following a suspicious mammogram.

We have put into place procedures for recruitment through the PHA clinical services. We will be able to identify women receiving breast biopsy procedures and who could be eligible for the study among those visiting the PHA participating hospitals. Pilot testing of recruitment techniques will begin January to February 2001.

b. Among those who say they are willing to participate, determine eligibility using the 18 criteria listed in section 4.1 of the proposal.

We have developed a simple eligibility screening form suitable for use in the large-scale screening of potential participants during a telephone interview. All other items subsumed under this Task, will be undertaken in the next year.

- c. Enroll the consecutive eligible women who have histologically confirmed stage I or II cancer of the breast.
- d. Enroll consecutive eligible women who are disease free in the high-risk (>10% in ten years according to the Gail/Benichou model) and meet all eligibility requirements of the study and are matched to the cases on age (within 5 years).
- e. Enroll consecutive eligible women who are disease free in the low-risk (<7% in ten years according to the Gail/Benichou model) and meet all eligibility requirements of the study <u>and</u> are matched to the cases on age (within 5 years).
- f. Ensure that the open biopsy material is processed and sent to Dr. Davis's laboratory.

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g. Collect data on lifestyle, demographic, and health (family and personal history) plus psychosocial factors as outlined in 4.4.3.

- h. Schedule the first clinic appointment for the purposes of collecting all of the blood and urine specimens and taking the anthropometric measurements.
- i. Abstract medical records for relevant health history and pathology data.
- j. Randomize to either intervention or control. Inform woman of this.
- k. If in the intervention, schedule the individual and group sessions with the dietitian.

Task 3: Intervention / Passive Follow Up in the Controls, Months 14-28:

a. Ensure that the intervention is delivered according to the protocol.

Through collaboration with a local cardiac rehabilitation center, we have access to an appropriate conference room and adjoining teaching kitchen.

- b. Encourage women randomized to the intervention to attend all of the sessions.
- c. Stay in contact with the control group to assure compliance with the follow-up measures.
- d. Schedule the follow-up visit at the Breast Clinic for the blood, urine, and anthropometric data collection.
- e. Schedule the visit for the needle biopsy at the Breast Clinic.
- f. Assure that all self-assessments are completed at follow up.

Task 4: Data Entry, Verification and Interim Analyses, Months 12-28:

- a. Assure that all data are immediately read into the tracking and analytic databases.
- b. Flag all outlier and illogical responses.
- c. Verify all outlier and illogical responses, re-contacting participants, if necessary.
- d. Conduct simple descriptive analyses (e.g., cross-tabulations and univariate statistics).

Task 5: Final Data Analyses, months 28-36:

- a. Perform all exploratory analyses to test for adherence to model assumptions.
- b. Perform all necessary data manipulations (e.g., log transforming all non-normal and heteroschedastic data).
- c. Test study hypotheses.
- d. Conduct post-hoc analyses of study data.
- e. Prepare manuscripts.
- f. Archive datasets for future analyses and future patient follow-up.
- f. Plan for future studies.

This concludes the Yearly Report for Year 1 of this study.

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Appendices

Appendix 1: Assessment Instruments Questionnaire

Personal Reaction Scale Social Approval Scale

Vegetable and Fruit Questionnaire

Appendix 2: Recruitment and Consent Letter of Introduction

Consent Form

Eligibility Screening

Brochure for Breast Clinics

Appendix 3: Collection & Processing Urine

Blood

Buccal cells

Body Size Measurements

Appendix 4: Intervention Materials Draft Syllabus

Diet Diary for Brassica

Food lists and dietary goals

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QUASI STUDY Demographics

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| | |

1. Please fill in the bubble that best describes the race for each of your parents

| | White | African - American | Hispanic | Native- American | Asian or Pacific Islander | Other |
|--|---------------|-----------------------|----------|---------------------|---------------------------------|-------|
| Mother | 0 | 0 | O | 0 | 0 | 0 |
| Father | 0 | 0 | 0 | 0 | 0 | 0 |
| you answered Other, please pecify: | Mother Father | | | | | |

| | r dulor |
|----|--|
| 2. | What is the highest year or level of school you have completed? (Select only one.) |
| | ○ 8th grade or less |
| | O More than 8th grade and less than high school |
| | ○ High school completed, no college |
| | O High school completed, some college (Associates degree, RN, etc.) |
| | ○ College completed (BS, BA, BSN, etc.) |
| | ○ More than college completed (MA, MS, PhD, etc.) |
| 3. | Are you presently employed? (Select only one.) |
| | ○ Yes, employed full time |
| | ○ Yes, employed part time |
| | ○ No (go to question #5) |
| | 4. If employed, how do you classify your present position? (Select only one.) |

| Skill or craft | Scientific/Technical work |
|--------------------|--|
| ○ Machine operator | ○ Service work |
| ○ Manual labor | ○ Clerical or office |
| ○ Sales | O Professional, managerial or administrative |
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| 5. | What is your current marital status? (Select only one.) | | | | | | | | | |
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| | | | | | | | | | | |
| | ○ Livi | ing with | a partner | | | | | | | |
| | ○ Wid | dowed (| go to page #4) | go to page #4) | | | | | | |
| | ○ Div | orced (| go to page #4) | e #4) | | | | | | |
| | ⊜ Se _l | parated | (go to page #4) | | | | | | | |
| | ○ Sin | Single, never married and not living with a partner (go to page #4) | | | | | | | | |
| | 6. | What i | t is the highest year or level of school your partner has completed? (Select one.) | | | | | | | |
| | | ○8th | grade or less | | | | | | | |
| | | ○ Mor | ore than 8th grade and less than high school | | | | | | | |
| | | ○ Hig | h school completed, no college | | | | | | | |
| | | ○ Hig | h school completed, some co | e college (Associates degree, RN, etc.) | | | | | | |
| | | ○ Col | lege completed (BS, BA, BS | BA, BSN, etc.) | | | | | | |
| | | ○ Moi | re than college completed (MA, MS, PhD, etc.) | | | | | | | |
| | 7. | ls you | ır partner presently employ | partner presently employed? (Select only one.) | | | | | | |
| | | ○ Yes | Yes, employed full time | | | | | | | |
| | | ○ Yes | es, employed part time | | | | | | | |
| | | ○ No (go to page #4) | | | | | | | | |
| | | 8. | If your partner is employe (Select only one.) | d, how do you classify his/her present position? | | | | | | |
| | | | ○ Skill or craft | ○ Scientific/Technical work | | | | | | |
| | | | | ○ Service work | | | | | | |
| | | | ○ Manual Labor | ○ Clerical or office | | | | | | |
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QUASI STUDY Food Frequency Questionnaire

The following questions relate to your eating or dietary habits including any various dietary or nutritional supplements you may take.

| | Date Form Completed | | | | | | | | |
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- How many meals per day do you usually eat? 1.
 - \bigcirc 0 $\bigcirc 1$

day?

2.

- \bigcirc 2
- \bigcirc 3
- - $\bigcirc 4$

How soon after you wake up do you have your first meal of the

- \bigcirc 5
- **O**6
- 07
- 08
- Hours
- 0 OOO O Minutes

O9

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- 3 000
- 4 000
- 5 000
- 6 000 7 000
- 8 000

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| 3. Which | ch meal | ∣is | usuall | y your | largest | meal? |
|----------|---------|-----|--------|--------|---------|-------|
|----------|---------|-----|--------|--------|---------|-------|

O 2nd ○ 1st

○ 3rd

O 4th

○ 6th ○ 5th

○ 7th

○ 8th

O9th

How many snacks do you usually have per day? (This does not include 4.

diet beverages, coffee, tea or water.)

1

2 3 00

5 00

6 7 8

During the past month have you taken any vitamins or minerals? 5.

- O No (go to page #8)
- O Yes, fairly regularly (at least one time per week)
- O Yes, but not regularly (go on to page #8)

During the past month, how often have you taken a 6. multi-vitamin?

Times per

O Day ○ Week

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7. Other than as part of a multi-vitamin, how often do you take single doses of the following?

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| 8 00 | |
| 9 00 | |

| Beta-carot | ene |
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| Times per 0 00 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 9 00 | O Day |

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| Vitamin E | |
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7. Other than as part of a multi-vitamin, how often do you take single doses of the following? (continued from previous page)

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| | Cod liver oil, other fish oils or | | | | | | | | | |
|---------------------|--------------------------------------|--------------------|--|--|--|--|--|--|--|--|
| omega-3 fatty acids | | | | | | | | | | |
| | Tim | _{les per} | | | | | | | | |
| 0 | 00 | ○ Week | | | | | | | | |
| 1 | 00 | | | | | | | | | |
| 2 | 00 | | | | | | | | | |
| 3 | 00 | | | | | | | | | |
| 4 | 00 | | | | | | | | | |
| 5 | 00 | | | | | | | | | |
| 6 | 0.0 | | | | | | | | | |
| 7 | 00 | | | | | | | | | |
| 8 | 00 | | | | | | | | | |
| 9 | 00 | | | | | | | | | |

| : | Yeast | |
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| 0 1 2 3 4 5 6 7 8 9 | Times pe | r ○ Day ○ Week |

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8. Do you take herbs or extracts?

- Yes
- No

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The next section of this questionnaire deals specifically with the type and amounts of the foods you eat.

- For each item, think about how often you ate that food, on average, over the last year.
- Please think about all meals, snacks and food eaten either at home or away from home.
- Please tell us only about the food that YOU eat, not the food you may prepare for family members or other people.

For each food item listed, please do the following.

- Fill in the bubble that corresponds to the number of times that you eat that food. If you have not eaten that food, please fill in the bubble for "Never".
- On the same line, please indicate your usual serving size for that food using the following guidelines.
 - The medium serving size (M) for that food is listed with the food description.
 - A small (S) serving size is about one-half (1/2) the size of a medium serving.
 - A large (L) serving size is about twice (2) the size of a medium serving.
 - It is important to remember that if you have eaten the food at least once, you will need to fill in one of the bubbles for your serving size.
 - It is also important that you accurately represent the amount of food that you have eaten. If your portion size is generally much more than the large serving size or much less than the small serving size, you must adjust both how often you eat the food and the portion size accordingly. Please count larger portions as extra portions (occuring more often) and smaller portions as fewer portions (occuring less often). The following examples explain this more clearly.

Here are several examples explaining how to fill out this section of the questionnaire.

Example 1 Suppose that you normally eat 2 cups of cooked broccoli about 3 times a week. The medium serving size for cooked broccoli is given as 1/2 cup which means that a large serving size would be 1 cup (twice 1/2 cup). Since your normal serving size of 2 cups is twice a large serving, this food should be counted as a large serving size eaten twice as often. Specifically, the chart should be filled out as a large portion size eaten 6 times a week (see chart below).

| Type of Food | | Average Intake Over the Last Year | | | | | | | | | | Your Serving Size | | |
|------------------------------|---|-----------------------------------|-------------------|-----------------|-----------------|-------------------|-------------------|-----------------|------------------|---|---|----------------------|--|--|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 | | |
| | | 1 Per Mo. | 2-3 Per Mo. | 1 Per Wk. | 2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2+ Per Day | S | M | L | | |
| Cooked broccoli (1/2 cup) | 0 | 0 | 0 | 0 | Ο | 0 | | O | Ο | Ο | 0 | • | | |

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Example 2 Suppose that you normally drink 1/2 cup of orange juice about once a week. Note than since there are 8 fluid ounces in a cup, your normal serving size of 1/2 cup is equivalent to 4 ounces. The medium serving size for orange juice is given as 6 ounces which means that a small serving size would be 3 ounces (half of 6 ounces). Since your normal serving size of 4 ounces is larger than a small serving size, this item should be counted as a medium serving size eaten once a week (see chart below).

| Type of Food | Average Intake Over the Last Year | | | | | | | | | Your Serving Size | | |
|----------------------|-----------------------------------|-----------------|-------------------|-----------------|-----------------|-------------------|-------------------|-----------------|------------------|----------------------|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 |
| | Never | 1 Per Mo. | 2-3 Per Mo. | 1 Per Wk. | 2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2+ Per Day | S | M | L |
| Orange juice (6 oz.) | Ö | Ö | 0 | • | Ο | O | Ο | O | O | Ο. | • | O |

Example 3 Suppose that you normally eat 3 cups of beef stew about 2 times a week. The medium serving size for beef stew is given as 1 cup. Since your normal serving size of 3 cups is three times a medium serving, this food could be counted as a medium serving size eaten three times as often. Specifically, the chart could be filled out as a medium portion size eaten 6 times a week (see first row in chart below).

Another alternative would be to report this food with a large serving size. Since the medium serving size for beef stew is given as 1 cup, a large serving size would be 2 cups (twice 1 cup). Since your normal serving size of 3 cups twice a week is equivalent to 6 cups a week, this food could be counted as 2 cups eaten three times a week. Specifically, the chart could be filled out as a large portion size eaten 3 times a week (see second row in chart below).

Use only <u>one</u> method when reporting this food. It does not matter which method is used because the information is equivalent for the purposes of this survey.

| | Average Intake Over the Last Year | | | | | | | | | | Your Serving Size | | | |
|--|-----------------------------------|-----------------|-------------------|-----------------|-----------------|-------------------|-------------------|-----------------|------------------|---|----------------------|---|--|--|
| Type of Food | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 | | |
| Type of Food | | 1 Per Mo. | 2-3 Per Mo. | 1 Per Wk. | 2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2+ Per Day | s | М | L | | |
| Beef stew, pot pie or gumbo with carrots or other vegetables (1 cup) | 0 | 0 | 0 | 0 | O | Ô | | O | O | 0 | | 0 | | |
| Beef stew, pot pie or gumbo with carrots or other vegetables (1 cup) | 0 | 0 | 0 | 0 | 0 | • | 0 | 0 | 0 | 0 | 0 | • | | |



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| | Average Intake Over the Last Year | | | | | | | | | | | Size |
|---|-----------------------------------|-----------------|-------------------|-----------------|-----------------|-------------------|-------------------|-----------------|------------------|--------------|---|---------|
| Type of Food | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 |
| 3. | Never | 1 Per Mo. | 2-3 Per Mo. | 1 Per Wk. | 2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2+ Per Day | S | М | L |
| FRUITS AND JUICES | | | | | | | | | | Same and the | San San English (San | NS 2012 |
| Apples, applesauce, pears (1 medium or 1/2 cup) | O | O | Ó | Q | Ο | O | Ο | O | 0 | Ó | 0 | 0 |
| Bananas (1 medium) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Peaches, apricots, nectarines (canned, frozen or dried) (1 medium or 1/2 cup) | O | 0 | 0 | Ο | O | 0 | 0 | O | Ο | Ο | O | O. |
| Peaches, apricots, nectarines (fresh) (1 medium or 1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cantaloupe, mango, papaya (1/4 medium) | O | O | O | O | O | O | O | Ô | O | O | 0 | О |
| Watermelon (1 medium slice or 1 cup) | 0 | 0 | 0 | 0 | <i>J</i> O | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Strawberries, kiwi (1/2 cup) | 0 | O | O | O | O | Ο | O. | 0 | O | 0 | Ο | O |
| Oranges, tangerines (1) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dried fruits (raisins, prunes, figs) (1/4 cup) | 0 | 0 | Ó | 0 | O | O | О | Ο | Ο | Ο | Ο | O |
| Grapefruits (1/2) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Any other fruit (other melons, grapes, berries, pineapples, fruit cocktail, etc.) (1/2 cup) | 0 | 0 | 0 | 0 | 0 | Ο | O | 0 | O | O | O | 0 |
| Orange juice (6 oz.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grapefruit juice (6 oz.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | O | О | 0 | 0 |
| Other fruit juice with vitamin C, fortified fruit drinks, Hi-C, Kool-Aid, cranberry juice, Tang (6 oz.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Any other fruit juice (apple juice, grape juice, punch, guava or other) (6 oz. | | 0 | Ο | Ο | O | 0 | О | 0 | O | O | Ο | O |

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| | | Ave | rage I | ast Ye | ar | | Your Serving Size | | | | | |
|---|-------|-----------------|-------------------|-----------------|-----------------|-------------------|----------------------|-----------------|------------------|-------------------|---------------|-----|
| Type of Food | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 |
| | Never | 1 Per Mo. | 2-3 Per Mo. | 1 Per Wk. | 2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2+ Per Day | s | М | L |
| VEGETABLES AND SIDE DISHE | S | | | | | | | | | This gay - manage | Delikeren Yus | |
| String beans, green beans (1/2 cup) | 0 | Ο | O | 0 | О | О | · O · | Ο | *O | Ο. | O" | .O. |
| Peas, snow peas (1/2 cup) | 0 | 0 | 0 | 0 | O. | 0 | 0 | 0 | 0 | Ο | 0 | 0 |
| Refried beans (as side dish, not including those in burritos, etc.) (1/2 cup) | O | 0 | Ó | Ô | O | Ο | 0 | O | Ο. | O | Ó. | О |
| Pinto, lima and butter beans (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Ο | 0 | 0 |
| Garbanzo, kidney or red beans; black eyed, yellow, split or Chinese peas (1/2 cup) | O | Ō | O | O | O | O | 0 | O | O | O | O | O |
| Lentils (1/2 cup) | 0 | 0 | 0 | 0 | 0 | Ō | 0 | 0 | 0 | 0 | 0 | 0 |
| Corn, hominy (1/2 cup or 1 medium ear) | О | 0 | 0 | 0 | Ο | O | Ο | Ο | Ο | O | 0 | 0. |
| Winter squash, acorn squash, other baked squash (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tomatoes, tomato juice (including pico de gallo or chopped tomatoes) (1/2 cup, 1 medium or 6 oz.) | | 0 | 0 | 0 | O | Ο | 0 | O | Ο, | O | O | O |
| Salsa picante, taco sauce (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Avocado, guacamole (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | Ο | 0 | Ο | O | 0 | 0 |
| Raw broccoli (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cooked broccoli (1/2 cup) | O | 0 | 0 | 0 | 0 | O | Ò | 0 | O | O | O | Ο |
| Cooked spinach (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cooked mustard greens, turnip greens, collards, kale, swiss chard, rutabaga, kohlrabi (1/2 cup) | 0 | 0 | 0 | 0 | 0 | O | O | Ο | 0 | 0 | 0 | O |
| Carrots or mixed vegetables containing carrots (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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| | Average Intake Over the Last Year | | | | | | | | | | Your Serving Size | | |
|--|-----------------------------------|-----------------|-------------------|-----------------|-----------------|-------------------|--------------------------|-----------------|------------------|-------------|----------------------|-----------|--|
| Type of Food | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 | |
| | Never | 1 Per Mo. | 2-3 Per Mo. | 1 Per Wk. | 2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2+ Per Day | S | M | L | |
| VEGETABLES AND SIDE DISHE | S (cor | ntinue | d) | | | | 5, ₆ , 8, 180 | na z tak Casar | Joan Friedon | Nacharias I | rezy, lado | C. W SIA. | |
| Cooked cabbage, cauliflower, brussel sprouts (1/2 cup) | O | Ο | O | O | Ο | O | Ö. | O | ,O | · O: | 0. | Ο | |
| Raw cabbage, cauliflower, brussel sprouts and Chinese cabbage (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Sauerkraut, pickled cabbage (1/2 cup) | О | Ο | O | O | Q | O | O | O | Ο | 0 | 0 | O | |
| Raw spinach (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Ο | 0 | 0 | 0 | |
| Other green salad (1/2 cup) | O | O | О | O | O | O | O | 0 | Ο | 0 | 0 | Ο | |
| Pasta salad, macaroni salad, potato salad with mayonnaise, salad dressing or oil (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Diet salad dressing, diet mayonnaise (including on sandwiches) (2 tablespoons) | O | Ο | O | 0 | Ο | O | 0 | O | Ο. | Ο | 0 | Ο | |
| Salad dressing, mayonnaise, tartar sauce (including on sandwiches) (2 tablespoons) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| French fries, fried potatoes, hash browns (3/4 cup) | 0 | 0 | О | 0 | Ο | 0 | O | 0 | 0 | Ο | 0 | Ο | |
| Sweet potatoes, yams (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Other potatoes (such as boiled, baked, mashed), turnips (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | O | 0 | 0 | Ο | 0 | 0 | |
| Rice (white) (3/4 cup | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Rice (brown or wild) (3/4 cup | 0 | 0 | 0 | 0 | 0 | 0 | Ô | O | 0. | О | Ω | 0 | |
| Rice (fried) (3/4 cup |) 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Pasta, noodles (including lo mein), couscous (plain, without cheese or tomato sauce) (3/4 cup | | 0 | 0 | 0 | О | 0 | Ο | Ο | Ο | Ο | 0 | 0 | |
| Butter, margarine or other fat on vegetables, potatoes, rice, etc. at the table (2 teaspoons or 2 pats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |

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| | | Ave | rage I | ntake | Over | the L | ast Ye | ar | | Your Serving Size | | | |
|---|--------|-----------------|-------------------|-----------------|-----------------|-------------------|-------------------|-----------------|------------------|----------------------|-------|--|--|
| Type of Food | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 | |
| | Never | 1 Per Mo. | 2-3 Per Mo. | 1 Per Wk. | 2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2+ Per Day | S | M | L | |
| VEGETABLES AND SIDE DISHE | S (cor | ntinue | d) | | | | | | | 200 000 00 | | | |
| Onions (1_medium or 1/2 cup) | Ο | 0 | 0 | Ö | 0 | O | Ο | Ο | 0 | Ο | · O · | ÷О; | |
| Garlic, chives or scallions (1 clove or 1 shake) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Olives (2 medium or 1 tablespoon chopped) | Ο | Ο | 0 | 0 | 0 | 0 | Ο | Ο | Ο | Ο | Ο | O | |
| Any other vegetable including summer squash, asparagus, sweet peppers, bok choy, okra, eggplant, beets, etc. (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| MEATS, FISH, POULTRY AND M | IXED | DISHE | S | | | | | | | | | C 12 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 | |
| Hamburgers, cheeseburgers, meat loaf (3 oz.) | O | 0 | 0 | Ο | 0 | Ο | 0 | 0 | Ο | Ο | Ο | 0 | |
| Beef (steaks, roasts, teriyaki, cube steak, beef on sandwiches, barbecue beef, etc.) (4 oz.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Beef stew, pot pie or gumbo with carrots or other vegetables (1 cup) | 0 | 0 | 0 | 0 | 0 | Ο | 0 | 0 | 0 | Ο | Ο | Ο | |
| Pork (chops, roasts, ribs, barbecue, teriyaki, breaded pork chops) (4 oz.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Mixed dish with beef or pork and rice (Oriental main dishes, Cajun jambalaya, Spanish rice) (1 cup) | 0 | 0 | Ο | 0 | 0 | 0 | Ó | 0 | 0 | 0 | 0 | 0 | |
| Ham, ham hocks (including ham on sandwiches) (4 oz.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Lamb, mutton, mutton stew, steaks or ribs (4 oz.) | 0 | 0.2 | 0 | 0 | 0 | 0 | O | 0 | 0 | 0 | Ο | Ο | |
| Game including venison, rabbit, possum, squirrel (4 oz.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Liver (chicken livers, other organ meats) (4 oz.) | 0 | 0 | 0 | 0 | Ο | 0 | 0 | Ο | 0 | O | Ο | 0 | |
| Chicken, turkey or wild fowl (roasted, broiled or ground including teriyaki and on sandwiches) (4 oz.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Chicken or turkey stew, pot pie or gumbo with carrots or other vegetables, chicken and dumplings (1 cup | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | O | O | Ο | |

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| | | Ave | rage I | ntake | Over | the L | ast Ye | ar | | Your Serving Size | | | |
|--|--------|-----------------|-------------------|-----------------|-----------------|-------------------|-------------------|-----------------|------------------|---|-----------|---|--|
| Type of Food | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 | |
| | Never | 1 Per Mo. | 2-3 Per Mo. | 1 Per Wk. | 2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2+ Per Day | S | M | L | |
| MEATS, FISH, POULTRY AND M | IXED I | DISHE | S (co | ntinu | ed) | | | | | 100 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | a. 738.55 | | |
| Mixed dish with chicken or tofu and rice (Oriental main dish, Cajun jambalaya) (1 cup) | O | O | 0 | O | Ο | Ο | 0 | Ο | O | Ō | 0 | O | |
| Fried chicken (2 small pieces or 1 large piece) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Ο | 0 | 0 | 0 | |
| Fried fish or fish sandwich (3 oz.) | Ο | O | Ο | О | Ο | O | 0 | 0 | Ο | 0 | Ö | O | |
| Tuna fish, salmon, sardines (raw tuna or salmon, tuna salad, tuna casserole) (1 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Shell fish (shrimp, lobster, crab, oysters, mussels, etc. including raw) (1/2 cup) | O | O | O | Ο | O | 0 | O | Ο | 0.* | Ο | Ô | 0 | |
| Other broiled, baked or raw fish (trout, sole, halibut, poke, grouper, etc.) (4 oz.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Mixed dish with seafood and rice (Oriental main dish, Cajun jambalaya) (1 cup) | 0 | Ο | Ο | 0 | Ο | 0 | Ο | Ο | Ο | 0. | 0 | 0 | |
| Fish stew or seafood gumbo (1 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Tofu, other soy and textured vegetable products (TVP) (1 cup) | | 0 | 0 | 0 | 0 | 0 | O | Ο | Ο | 0 | О | Ο | |
| Spaghetti, lasagna, other pasta dishes with tomato and meat sauce (1 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Spaghetti, lasagna, other pasta dishes with tomato sauce and no meat sauce (1 cup) | 0 | 0 | 0 | 0 | 0 | 0 | O | Ο | 0 | O | 0 | 0 | |
| Pizza (2 slices) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Mixed dishes with cheese but no tomato sauce (including macaroni and cheese, chile rellenos, cheese quesadillas, quiche) | | 0 | 0 | Ο | Ο | Ο | Ο | O | Ο | · O | O | Ο | |
| Burritos including breakfast burritos, soft tacos with flour tortillas (2) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |

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| | | Ave | rage I | ntake | Over | the La | ast Ye | ar | | Your Serving Size | | | |
|--|---------------|-----------------|-------------------|-----------------|-----------------|-------------------|-------------------|-----------------|------------------|--|---------------|---------------------------------------|--|
| Type of Food | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 | |
| .,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | Never | 1 Per Mo. | 2-3 Per Mo. | 1 Per Wk. | 2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2+ Per Day | S | M | L | |
| MEATS, FISH, POULTRY AND M | IXED | DISHE | S (co | ntinu | ed) | | TOTAL SECTION | Organista I | V. (A.N. 888. 1 | ال مصلافات | y (22%) si -1 | Jak Sala | |
| Enchiladas, tamales, tacos, tostadas, chalupas, other Mexican dishes with corn tortillas including nachos with chile and cheese (2) | O | O | O | Ó | O | O | О | 0 | O | Ο | Ο. | O | |
| Red chile con carne (1 cup, 1/2 cup as condiment) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Green chile con carne (1 cup, 1/2 cup as condiment) | Ю | O | O | O | O | О | Ο | O | O | Ο | 0 | 0. | |
| Gravies made with meat drippings or white sauce (1/4 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| LUNCH ITEMS | | | | | | | | KAD 1 | · · patient dame | \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ | *55 C**** | rake rake | |
| Hot dogs (pork, beef or turkey; include regular, low-fat and non-fat) (2) | O | 0 | 0 | 0 | O | О | O | Ο | O | O | O | Ο | |
| Bologna, salami, Spam, other lunch meats excluding ham (include regular, low-fat and non-fat) (2 oz. or 2 slices) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Vegetable and tomato soup (including vegetable beef, minestrone) (1 cup) | $\overline{}$ | 0 | 0 | 0 | 0 | О | O | 0, | Ο | O | 0 | Ο | |
| Other broth-based soups (including chicken noodle soup, tortilla soup, egg drop soup, wonton soup) (1 cup) | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Bean soups (including pea, lentil, black bean) (1 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Ο | Ο | 0. | |
| Cream soups such as chowders, potato, tomato, cheese (1 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| BREAD, SALTY SNACKS, SPRE | ADS | | | | 1 | | 1 | | T | | 17 Day 2842 | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | |
| White bread (including sandwiches, hamburger or hot dog buns, bagels, baguettes, pita bread, English muffins, French bread) (2 slices | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Ο | O | O | 0 | Ο | |
| Dark bread (including whole wheat, rye, pumpernickel, other high-fiber bread) (2 slices | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Biscuits, scones, croissants, muffins (2 biscuits or 1 muffin | , 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | O | 0 | |
| Corn bread, corn muffins (1 medium piece |) 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |

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| | Average Intake Over the Last Year | | | | | | | | | Your Serving Size | | |
|---|-----------------------------------|-----------------|-------------------|-----------------|-----------------|-------------------|-------------------|-----------------|------------------|----------------------|---|------|
| Type of Food | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 |
| | | 1 Per Mo. | 2-3 Per Mo. | 1 Per Wk. | 2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2+ Per Day | s | M | L |
| BREAD, SALTY SNACKS, SPREA | ADS (d | contin | ued) | | | | | | | | | Ga G |
| Fry bread, hush puppies, fritter (2 medium pieces) | Ö | Ο | O | O | 0 | 0 | Ο. | 0. | 0 | 0 | 0 | O |
| Flour tortilla (by itself, not in burritos, etc.) (2) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Ο | 0 | 0 | 0 |
| Corn tortilla (by itself, not in enchiladas, etc.) (2 medium) | O | Ο | O | O | Ο | О | O | O | 0 | Ο | Ο | Ο |
| Other snacks such as crackers, potato chips, corn chips, tortilla chips, pretzels, popcorn (include regular, low-fat and non-fat) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Nuts and seeds including peanuts, peanut butter, sunflower seeds (2 tablespoons) | O | O | O | Ο | O | O | Ο | - O | Ο | O | Ο | Ο |
| Margarine on bread or roll (2 teaspoons) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Butter on bread or roll (2 teaspoons) | 0 | 0 | 0 | 0 | O | O | O | Ο | O | Ο | Q | O |
| BREAKFAST FOODS | | | | | | | | | T | | | r · |
| High fiber, bran or granola cereals, shredded wheat (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Highly fortified cereals such as Product 19, Total or Most (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | O | Ο | 0 | 0 | 0 | 0 |
| Cold cereals that are low in sugar such as Corn Flakes, Rice Krispies, Kix (1/2 cup | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Sweetened cold cereals such as Frosted Flakes, Fruit Loops (1/2 cup) | | 0 | 0 | 0 | 0 | Ο | 0 | Ο | 0 | 0 | 0 | 0 |
| Cooked cereals (including grits, oatmeal, cream of wheat) (1/2 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Sugar, molasses or honey added to cereal (2 teaspoons) | 0 | 0 | 0 | 0 | Ο | O | Ο | 0 | 0 | 0 | Ο | 0 |
| Eggs, omelettes (2 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Bacon (regular, low-fat and non-fat) (2 slices | 0 | 0 | 0 | 0 | 0 | Ο | 0 | 0 | O | O | Ο | 0 |

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| | | Ave | rage I | ntake | Over | the La | ast Ye | ar | | | Your ving S | ize |
|---|---|-----------------|-------------------|-----------------|-----------------|-------------------|-------------------|-----------------|------------------|------------------|--|-------------|
| Type of Food | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 |
| Type of Food | | 1 Per Mo. | 2-3 Per Mo. | 1 Per Wk. | 2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2+ Per Day | S | M | L |
| BREAKFAST FOODS (continued) |) | | | | | | | | acomo sensi | J. 18 40. feat 1 | | |
| Sausage (regular, low-fat and non-fat) (1 patty or 2 links) | O | 0 | O | Ο | Ο | Ο | 0 | 0 | 0 | О | .O. | 0 |
| Pancakes, waffles, French toast (1 medium piece) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SWEETS | | | | | | | | | | | ************************************** | . 7 2026 70 |
| lce cream (1 scoop or 3/4 cup) | Ô | Ο | Ο | O | Ο | 0 | O | Ο | O | O | Ο | O |
| Frozen yogurt, low-fat ice cream, ice milk (1 scoop or 3/4 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Ο | 0 |
| Doughnuts, cookies, cakes, pastry, Pop Tarts, brownies (1 or 3 small cookies) | O | Ο | O | Ο | O | Ο | Ο | Ο | Ο | Ο | O | O |
| Pudding, custard, rice pudding (1 scoop or 3/4 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pumpkin pie, sweet potato pie (1 medium slice | 0 | 0 | 0 | O | O | O | 0 | 0 | 0 | 0 | Ο | O |
| Other pies (1 medium slice | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chocolate including Hershey's kisses, M&M's, chocolate candy bars (1 small slice or 1 oz. | 0 | 0 | 0 | 0 | O | O | Ο | 0 | O | O | O | Ο |
| Other candy, jelly, honey, brown sugar jams, or molasses (including on bread or other foods) (3 pieces or 1 tablespoon | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DAIRY PRODUCTS | | | | | | | | T | , | *** | Cra A. e. | 10, 44 |
| Cottage cheese, ricotta cheese (include regular, low-fat and non-fat) (1/2 cup | | 0 | 0 | 0 | Ο | Ο | Ο | 0 | Ο | Ο | O | 0 |
| Cheese (cheddar, American, cream cheese, parmesan, Velveeta, cheese spreads including cheese on sandwiches or as snacks; include regular, low-fat and non-fat) (2 oz. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0. | 0 | 0 | 0 | 0 |
| Plain yogurt (unflavored) (1 cup | | 0 | 0 | 0 | 0 | 0 | 0 | Ο | 0 | 0 | 0 | Ο |
| Flavored yogurt (regular, low-fat and non-fat) (1 cup | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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Please note that the choices for "Average Intake Over the Last Year" are different for beverages. When considering alcoholic beverages, please remember that all of your answers will be kept confidential.

| | | Ave | rage I | ntake | Over | the L | ast Ye | ear | | Ser | Your ving \$ | rour /ing Size | |
|---|-------|-------------------|-----------------|-------------------|-------------------|-----------------|-------------------|-------------------|------------------|-----|-----------------|-------------------|--|
| Type of Food | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 | 3 | |
| | Never | 1-3 Per Mo. | 1 Per Wk. | 2-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 2-3 Per Day | 4-5 Per Day | 6+ Per Day | S | M | L | |
| BEVERAGES | | | | | | | | | | | | | |
| Whole milk, beverages with whole milk (not including milk on cereal) (1 cup) | | Ο | Ο | Ο | O | O | Ο | O | Ο. | O | Ō | Ο | |
| 2% milk and beverages with 2% milk (not including milk on cereal) (1 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Skim milk, 1% milk or buttermilk and beverages made with these (not including milk on cereal) (1 cup) | O | Ō | O | Ο | Ο | O | O | Ο | O | O | 0 | O | |
| Soy milk and beverages with soy milk (not including milk on cereal) (1 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Instant breakfast, Ensure or Slimfast (12 oz.) | Ο | 0 | Ο | Ο | Ο | 0 | Ο | Ο | Ο | 0 | O | Ο | |
| Regular soft drinks (including colas, 7-Up, etc.) (12 oz.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Diet soft drinks, unsweetened mineral water (12 oz.) | | 0 | O | О | Ο | 0 | Ο | Ο | · O | Ô | Ο | 0 | |
| Lemonade, sweetened mineral water (1 cup) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Coffee (regular or decaffeinated including espresso), tea (hot or iced including black tea, herbal tea and green tea) (1 cup) | 0 | 0 | 0 | 0 | 0 | 0 | О | Ο | 0 | 0 | Ο | Ο | |
| Non-dairy creamer in coffee or tea (1 tablespoon) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Milk in coffee or tea (2 tablespoons) | | 0 | | 0 | 0 | 0 | 0 | | 0 | Ο | 0 | 0 | |
| Cream (real) or half-and-half in coffee or tea (1 tablespoon | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Sugar in coffee or tea or honey in tea (not including artificial sweeteners) (1 teaspoon | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | O' | Ο | Ο | 0 | |
| Beer (12 oz.) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Wine (5 oz. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Hard liquor (including mixed drinks) (a 1 oz. shot |) 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |

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In the spaces below, please list any foods that you eat at least once per week (even in small quantities) that were not listed on the previous pages. Also, please indicate the typical serving size of that food you eat as well as how often you eat the food. Please note that the line for "soy nuts" is used as an example only.

| | | Average Intake Over the Last Year | | | | | | | |
|--|-------------------------|-----------------------------------|----------------------|------------------------|-------------------|----------------------|-----------------------|--|--|
| Food Description | Typical Serving Size | 3 1 Per Wk. | 4 2 Per Wk. | 5 3-4 Per Wk. | 5-6 Per Wk. | 7 1 Per Day | 8 2+ Per Day | | |
| SOY NUTS (for example purposes only) | 1/2 cup | O | | Ó | O | 0 | 0 | | |
| AND AND THE MEDICAL CONTROL OF THE C | | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | | O | 0 | 0 | О. | O | 0 | | |
| | 300 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | | O | О | О | O | Ο | 0 | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | | |

Please indicate the response that best describes your eating and cooking habits.

| | How Often Over the Last Year | | | | | | | | | | |
|--|------------------------------|-------------------|-------------------|-------------------|-----------------|---------------------|-----------------|-----------------|------------------|--|--|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | | |
| | Less than 1 Per Wk. | 1-2 Per Wk. | 3-4 Per Wk. | 5-6 Per Wk. | 1 Per Day | 1 1/2 Per Day | 2 Per Day | 3 Per Day | 4+ Per Day | | |
| How often do you eat in a fast food establishment such as McDonald's, BoJangles, etc.? | 0 | 0 | 0 | Ο | O | O | O | O | Ο | | |
| How often is fat or oil used in cooking the foods you eat such as in sauteing, stir frying or frying eggs, meat or vegetables? | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Not counting salads or potatoes, about how often do you eat vegetables? | 0 | 0 | 0 | O | 0 | 0 | Ο | 0 | Ο | | |
| About how often do you eat cold cereal? | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Not counting juices, how often do you eat fruit? | 0 | 0 | 0 | 0 | 0 | 0 | O | 0 | O | | |

| What kind of fat or oil is usually used in on the sauteing, stir frying or frying food.) | cooking? (You may select up to two fats used in |
|--|---|
| O Don't know | ◯ Pam or no oil |
| ○ Soft margarine (tub or liquid) | Olive or canola oil |
| Stick margarine or shortening | ○ Sesame or peanut oil |
| ◯ Butter, ghee | Other oil (such as coconut oil) |
| ○ Lard, fatback, bacon fat, fat from hamburg | ger |
| O Vegetable oil including soy, corn, sunflow | er, or safflower oil |
| If you eat refried beans or pinto beans, w (You may select up to two choices.) | hat kind of oil or fat is used in cooking the beans? |
| O Don't know / Don't eat beans | ○ Pam or no oil |
| ◯ Soft margarine (tub or liquid) | Olive or canola oil |
| ○ Stick margarine or shortening | ○ Sesame or peanut oil |
| O Butter, ghee | Other oil (such as coconut oil) |
| ○ Lard, fatback, bacon fat, fat from hambur | ger |
| O Vegetable oil including soy, corn, sunflow | ver, or safflower oil |
| What kind of fat do you <i>usually</i> add to veup to two choices.) | egetables, potatoes, etc. at the table? (You may select |
| O Don't add fat | O Lard, fatback, bacon fat |
| ○ Soft margarine (tub or liquid) | Olive or canola oil |
| ○ Stick margarine or shortening | ○ Sesame or peanut oil |
| O Butter, ghee | Other oil (such as coconut oil) |
| O Half butter, half margarine | |
| O Vegetable oil including soy, corn, sunflow | ver, or safflower oil |
| If you eat canned or frozen fruit, how is i | |
| O Unsweetened or in fruit juice | |
| ○ In light syrup | |
| ○ In heavy syrup | |

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Please indicate how often (Never, Seldom, Sometimes, or Often/Always) you do the following when you eat the foods listed. If you do not eat the food listed, then fill in the bubble in the first column indicating that you do not eat the food (this applies to all questions except the last one on salt use).

| | 0 Don't Eat | 1 Never | 2 Seldom | 3 Sometimes | 4 Often/ Always |
|--|----------------|------------|-------------|----------------|-----------------------|
| If you eat chicken, how often do you eat the skin on chicken? | | O | - O | O | O |
| If you eat meat, how often do you eat the fat on meat? | 0 | 0 | 0 | 0 | Ο |
| If you eat ground beef, how often do you use lean or extra lean ground beef? | O | O | O | Ο | O |
| If you eat hot dogs, bologna or other lunch meats, how often do you eat low-fat lunch meats? | 0 | 0 | 0 | 0 | 0 |
| lf you eat snacks such as chips or popcorn, how often do you eat low-fat chips, etc.? | 0 | O | O | О | O |
| If you eat bacon or sausage, how often do you eat low-fat bacon or sausage? | 0 | 0 | 0 | 0 | 0 |
| If you eat cheese (cottage cheese, cheddar cheese, cream cheese, American, etc.), how often do you eat low-fat cheese? | 0 | 0 | 0 | O | Ο |
| If you eat yogurt, how often do you eat low-fat yogurt? | 0 | 0 | 0 | 0 | 0 |
| If you eat cookies or cake, how often do you eat low-fat cookies or cakes? | 0 | 0 | Ο | 0 | О |
| How often do you add salt to your food at the table? | | 0 | 0 | 0 | 0 |

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QUASI STUDY Personal Reaction Inventory

| Date Form Completed | | | | | | | |
|---------------------|---|-----|---|------|--|--|--|
| Month | 1 | Day | 1 | Year | | | |
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DIRECTIONS: Listed below are a number of statements concerning personal attitudes and traits. Read each item and decide whether the statement is true or false as it pertains to you personally. Please darken the circle for true or for false. Please respond to each item. Do not leave any blank.

| STATEMENT | True | False |
|---|------|-------|
| Before voting, I thoroughly investigate the qualifications of all of the candidates. | O | O |
| 2. I never hesitate to go out of my way to help someone in trouble. | 0 | 0 |
| 3. It is sometimes hard for me to go on with my work if I am not encouraged. | 0 | O, |
| 4. I have never intensely disliked anyone. | 0 | 10 |
| 5. On occasion I have had doubts about my ability to succeed in life. | O | Ο |
| 6. I sometimes feel resentful when I don't get my way. | 0 | 0 |
| 7. I am always careful about my manner of dress. | O | O |
| 8. My table manners at home are as good as when I eat out in a restaurant. | 0 | 0 |
| 9. If I could get into a movie without paying and be sure I was not seen, I would probably do it. | O | 0 |
| On a few occasions, I have given up doing something because I thought too little of my ability. | 0 | .0 |
| 11. I like to gossip at times. | O | O |
| 12. There have been times when I felt like rebelling against people in authority even though I knew they were right. | 0 | 0 |
| 13. No matter who I am talking to, I am always a good listener. | O | O |
| 14. I can remember "playing sick" to get out of something. | 0 | 0 |
| 15. There have been occasions when I took advantage of someone. | | O |

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|--|----|--|--|--|--|--|--|--|

| | STATEMENT | True | False |
|-----|--|------|-------|
| 16. | I am always willing to admit it when I make a mistake. | O | O |
| 17. | I always try to practice what I preach. | 0 | 0 |
| 18. | I don't find it particularly difficult to get along with loud-mouthed, obnoxious people. | O | Ο |
| 19. | I sometimes try to get even rather than forgive and forget. | 0 | 0 |
| 20. | When I don't know something, I don't at all mind admitting it. | O | Ο |
| 21. | I am always courteous, even to people who are disagreeable. | 0 | 0 |
| 22. | At times I have really insisted on having things my own way | Ó | O |
| 23. | There have been occasions when I have felt like smashing things. | 0 | 0 |
| 24. | I would never think of letting someone else be punished for my wrong doings. | O | O |
| 25. | I never resent being able to return a favor. | 0 | 0 |
| 26. | I have never been irked when people expressed ideas very different from my own. | 0 | · O |
| 27. | I never make a long trip without checking the safety of my car. | 0 | 0 |
| 28. | There have been times when I was quite jealous of the good fortune of others. | O | Ó |
| 29. | I have almost never felt the urge to tell someone off. | 0 | 0 |
| 30. | I am sometimes irritated by people who ask favors of me. | O | 0 |
| 31. | I have never felt that I was punished without cause. | 0 | 0 |
| 32. | I sometimes think when people have misfortune they only get what they deserve. | O | O |
| 33. | I have never deliberately said something that hurt someone's feelings. | 0 | 0 |

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QUASI STUDY Social Approval

| Date Form Completed | | | | | | | | |
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| Month | 1 | Day | 1 | Year | | | | |
| | /[| | 1 | | | | | |

DIRECTIONS: Below are twenty statements. Please rate how much you agree with each using the following scale. Please darken the circle for disagree strongly, for disagree, for no opinion, for agree, or for agree strongly. Please respond to each item. Do not leave any blank.

| STATEMENT | Disagree Strongly | Disagree | No Opinion | Agree | Agree Strongly |
|---|----------------------|----------|---------------|-------|-------------------|
| Depending upon the people involved, I react to the same situation in different ways. | Ö | O | O | Q | O |
| I would rather be myself than be well thought of. | 0 | 0 | Ο | 0 | O |
| Many time I feel like just flipping a coin in order to decide what I should do. | 0 | O | O | 0 | 0 |
| 4. I change my opinion (or the way that I do things) in order to please someone else. | 0 | 0 | 0 | 0 | 0 |
| 5. In order to get along and be liked, I tend to be what people expect me to be. | O | O | Ô | O | 0 |
| 6. I find it difficult to talk about my ideas if they are contrary to group opinion. | 0 | 0 | 0 | 0 | 0 |
| 7. One should avoid doing things in public which appear to be wrong to others, even though one knows that he/she is right. | O | O | O | 0 | O - |
| 8. Sometimes I feel that I don't have enough control over the direction that my life is taking. | 0 | 0 | 0 | 0 | 0 |
| 9. It is better to be humble than assertive when dealing with people. | 0 | 0 | Ö | O | 0 |
| 10. I am willing to argue only if I know that my friends will back me up. | 0 | 0 | 0 | 0 | 0 |
| 11. If I hear that someone expresses a poor opinion of me, I do my best the next time that I see this person to make a good impression. | 0 | O | O | O | O |

| | STATEMENT | Disagree Strongly | Disagree | No Opinion | Agree | Agree Strongly |
|-----|---|----------------------|----------|---------------|-------|-------------------|
| 12. | I seldom feel the need to make excuses or apologize for my behavior. | Ó | O | Ô | O | O |
| 13. | It is not important to me that I behave "properly" in social situations. | 0 | 0 | 0 | O | Ο |
| 14. | The best way to handle people is to agree with them and tell them what they want to hear. | O | Ō | O | O | O |
| 15. | It is hard for me to go on with my work if I am not encouraged to do so. | 0 | 0 | 0 | 0 | 0 |
| 16. | If there is any criticism or anyone says anything about me, I can take it. | Ο | Ο | Ο | Ο | Ο |
| 17. | It is wise to flatter important people. | 0 | 0 | 0 | 0 | 0 |
| 18. | I am careful at parties and social gatherings for fear that I will do or say things that others won't like. | O | Ö | O | O | O |
| 19. | I usually do not change my position when people disagree with me. | 0 | 0 | 0 | 0 | 0 |
| 20. | How many friends you have depends on how nice a person you are. | 0 | O | O | O | 0 |

| 60 | 6 | 9 | 4 | 7 | 6 | 8 | 3 | 9 | |
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QUASI STUDY Beck A

| Date For | n Con | npl | eted |
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| Month / | Day | 1 | Year |
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DIRECTIONS: Below is a list of common symptoms of anxiety. Please read each item in the list carefully. Indicate how much you have been bothered by each symptom during the <u>PAST WEEK, INCLUDING TODAY</u>.

| SYMPTOMS | Not at All | Mildly It did not bother me much | Moderately It was very unpleasant but I could stand it | Severely I could barely stand it |
|--|------------|----------------------------------|--|---|
| 1. Numbness or tingling | 0 | O | O | О |
| 2. Feeling hot | 0 | 0 | 0 | 0 |
| 3. Wobbliness in legs | O | Ο | . O | O |
| 4. Unable to relax | 0 | 0 | 0 | 0 |
| 5. Fear of the worst happening | | 0 | · O | О |
| 6. Dizzy or lightheaded | 0 | 0 | 0 | 0 |
| 7. Heart pounding or racing | 0 | O | Ο | O |
| 8. Unsteady | 0 | 0 | 0 | 0 |
| 9. Terrified | 0 | 0 | Ο | O |
| 10. Nervous | 0 | 0 | 0 | 0 |
| 11. Feelings of choking | 0 | O - 1 | O | 0 |
| 12. Hands trembling | 0 | 0 | 0 | 0 |
| 13. Shaky | 0 | 0 | 0 | Ο |
| 14. Fear of losing control | 0 | 0 | 0 | 0 |
| 15. Difficulty breathing | 0 | 0 1 1 1 1 | O | Ô |
| 16. Fear of dying | 0 | 0 | 0 | 0 |
| 17. Scared | 0 | 0 | Ο | Ο |
| 18. Indigestion or discomfort in abdomen | 0 | 0 | 0 | 0 |
| 19. Faint | 0 | 0 | Ο | O |
| 20. Face flushed | 0 | 0 | 0 | 0 |
| 21. Sweating (not due to heat) | 0 | 4 24 O 1 1 1 1 1 1 1 | Ο | O |

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QUASI STUDY Physical Activity in Last Year

| Date Form Completed | |
|---------------------|--|
| Month / Day / Year | |
| | |

DIRECTIONS:

Think about your physical activity patterns over the past year (last 12 months).

On the next several pages, record information about the activities you did at home, at work, in volunteer activities outside the home, for exercise or recreation and during your free time.

For each activity category below, please record whether or not you did the activity within the last year.

If you did that activity, please also record only one choice for each of the following:

- (1) the number of months in the last year you did the activity,
- (2) how often (per month or per week) you did the activity, and
- (3) how many minutes or hours each day you spent doing the activity, excluding any breaks taken during the activity.

If you did not do a listed activity, please mark "No" and continue with the next activity.

EXAMPLE: In the example below, light household activity was reported 7-9 months per year on 1-2 days per week for 11-20 minutes each day.

| | | mor | | did | - | | did | w of you activ | 5.00 | | | mir | nute | nany s ea o th | ch c | lay o | bib | |
|--|--|------------|------------|------------|--------------|--------------------|--------------------|----------------------------|-------------------|-------------------|----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-------------------|-------------------|------------------|
| ACTIVITY | Did you do the activity in the last year? | 1-3 Months | 4-6 Months | 7-9 Months | 10-12 Months | 0-1 Days per Month | 2-3 Days per Month | 1-2 Days per Week | 3-4 Days per Week | 5-7 Days per Week | 1-10 Minutes per Day | 11-20 Minutes per Day | 21-30 Minutes per Day | 31-40 Minutes per Day | 41-60 Minutes per Day | 1-2 Hours per Day | 3-4 Hours per Day | 5+ Hours per Day |
| HOUSEHOLD CHOR | ES | | | | | | | 75 (1) 15 (2) 15 (2) | | | | | | | | | | |
| Light effort: cooking, cleaning up, laundry, dusting | ● Yes ○ No | 0 | 0 | • | 0 | 0 | 0 | • | O | 0 | 0 | • | 0 | 0 | 0 | 0 | 0 | 0 |

Please begin on the next page (Household Chores).

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| | | mor | nths | man did activ | you | | did | w off you activ | atalan 1997 | | | mir | nute | nany s ea o the | ch d | lay c | bib | |
|--|--|------------|------------|---------------------|--------------|-------------------------|--------------------|-----------------------|-------------------|-------------------|----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-------------------|-------------------|------------------|
| ACTIVITY | Did you do the activity in the last year? | 1-3 Months | 4-6 Months | 7-9 Months | 10-12 Months | 0-1 Days per Month | 2-3 Days per Month | 1-2 Days per Week | 3-4 Days per Week | 5-7 Days per Week | 1-10 Minutes per Day | 11-20 Minutes per Day | 21-30 Minutes per Day | 31-40 Minutes per Day | 41-60 Minutes per Day | 1-2 Hours per Day | 3-4 Hours per Day | 5+ Hours per Day |
| HOUSEHOLD CHOR | ES | | | | | erine Peril Peril | | | | | | | | | | | | |
| Light effort: cooking, cleaning up, laundry, dusting | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | 0 | Ó | Ο | O | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Moderate or vigorous effort: scrubbing, vacuuming, repairs, mopping, washing car | ⊖ Yes ⊝ No | 0 | 0 | 0 | 0 | O | 0 | O | O | Ο | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| LAWN AND GARDEN | N OR FARI | MINC | 3 | S | | | | | | | | | | | | | | |
| Light effort: watering lawn, picking flowers or vegetables | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | O | O | 0 | O | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Moderate effort: weeding, sweeping, raking, mowing (walking) | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | O | 0 | O | O | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vigorous effort: shoveling, digging, pruning, chopping wood | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | Ο | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CARING FOR CHILD | REN, ADU | ıLTS | OR | ANI | MAL | s | | | | | | | | | , selections. | | | |
| Light effort: bathing, feeding, playing with child or animal | ○ Yes ○ No | 0 | 0 | O | 0 | 0 | 0 | 0 | Ο | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Moderate effort: lifting and carrying, pushing wheelchair or stroller | ○ Yes ○ No | 0 | 0 | 0 | 0 | Ο | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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|----|--|--|--|--|--|--|--|

| | | mor | nths | man did ctiv | you | | did | v off you ictiv | do | | | mir | ute | nany s ea o the | ch d | lay c | bik | |
|---|--|------------|------------|--------------------|--------------|--------------------|--------------------|-----------------------|-------------------|-------------------|----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-------------------|-------------------|------------------|
| ACTIVITY | Did you do the activity in the last year? | 1-3 Months | 4-6 Months | 7-9 Months | 10-12 Months | 0-1 Days per Month | 2-3 Days per Month | 1-2 Days per Week | 3-4 Days per Week | 5-7 Days per Week | 1-10 Minutes per Day | 11-20 Minutes per Day | 21-30 Minutes per Day | 31-40 Minutes per Day | 41-60 Minutes per Day | 1-2 Hours per Day | 3-4 Hours per Day | 5+ Hours per Day |
| RECREATIONAL, EX | (ERCISE A | ND | SPO | RTS | | | | | | | | | | | Zeka Zeka | | | |
| Walking for exercise (not at work) | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | Ο | Ο | O | Ο | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dancing (social or folk dancing) | ○ Yes ○ No | 0 | 0 | 0 | 0 | Ο | 0 | O | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Sports - moderate effort: golf, softball, doubles tennis | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | O | O | O | O | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Sports - vigorous effort: basketball, soccer, singles tennis, racquetball | ○ Yes ○ No | 0 | 0 | 0 | 0 | Ο | 0 | | 0 | Q. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Conditioning exercises - moderate effort: low impact aerobics, health club machines | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | 0 | | Ο | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Conditioning exercises - vigorous effort: step aerobics, run/jogging, karate, swimming laps | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | 0 | O | Ο | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Strengthening exercises: lifting weights, strength training | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Ο | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Spiritual Exercises: Tai Chi, Yoga, Qi Qong | ○ Yes○ No | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

|--|

| | | | How many months did you do the activity? | | | How often did you do the activity? | | | | | How many hours or minutes each day did you do the activity? | | | | | | | |
|---|--|------------|--|------------|--------------|------------------------------------|--------------------|-------------------|-------------------|-------------------|---|-----------------------|-----------------------|-----------------------|-------------------|-------------------|-------------------|------------------|
| ACTIVITY | Did you do the activity in the last year? | 1-3 Months | 4-6 Months | 7-9 Months | 10-12 Months | 0-1 Days per Month | 2-3 Days per Month | 1-2 Days per Week | 3-4 Days per Week | 5-7 Days per Week | 1-15 Minutes per Day | 16-30 Minutes per Day | 31-45 Minutes per Day | 46-60 Minutes per Day | 1-2 Hours per Day | 3-5 Hours per Day | 6-8 Hours per Day | 9+ Hours per Day |
| OCCUPATIONAL AC | TIVITY (or | າly in | clud | e ac | tivitie | es W | hile | work | ting (| o ea | ırn n | none | ;y) | | | | | |
| Sitting - light effort: desk or computer work, lab work | ⊖ Yes ⊝ No | 0 | 0 | 0 | 0 | Ο | O | Ο | O | Ο | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Standing - light effort: slow walking, filing, copying, clerking, light assembly | ○Yes ○No | 0 | 0 | 0 | 0 | Ο | O | O | O | O | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Standing - moderate effort: brisk walking, waiting tables, nursing, custodial work, making deliveries | ○ Yes ○ No | 0 | 0 | 0 | 0 | Ο | 0 | 0 | 0 | O, | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Standing - vigorous effort: manual labor, loading trucks, farming | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | 0 | O | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| VOLUNTEER ACTIV | İTY | | | | | | 4 | | | | | | | | | | | |
| Sitting - light effort: desk or computer work, lab work | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Standing - light effort: slow walking, filing, copying, clerking, light assembly | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Standing - moderate effort: brisk walking, waiting tables, nursing, custodial work, making deliveries | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Ο | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Standing - vigorous effort: manual labor, loading trucks, farming | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |



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| | How many months did you do the activity? | | | | | How often did you do the activity? | | | | How many hours or minutes each day did you do the activity? | | | | | | | | |
|--|--|------------|------------|------------|--------------|------------------------------------|--------------------|-------------------|-------------------|---|----------------------|-----------------------|-----------------------|-----------------------|-------------------|-------------------|-------------------|------------------|
| ACTIVITY | Did you do the activity in the last year? | 1-3 Months | 4-6 Months | 7-9 Months | 10-12 Months | 0-1 Days per Month | 2-3 Days per Month | 1-2 Days per Week | 3-4 Days per Week | 5-7 Days per Week | 1-15 Minutes per Day | 16-30 Minutes per Day | 31-45 Minutes per Day | 46-60 Minutes per Day | 1-2 Hours per Day | 3-5 Hours per Day | 6-8 Hours per Day | 9+ Hours per Day |
| SITTING ACTIVITIES | | | | | | | | | | | | | | | | | | |
| Transportation: driving or riding to work (in car, bus or train) | ○ Yes ○ No | 0 | 0 | 0 | 0 | O | O | O | O | Ο | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Transportation: driving or riding to do chores or errands (in car, bus or train) | ○ Yes ○ No | 0 | 0 | 0 | 0 | O | O | O | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Watch TV or VCR: sitting | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | O | 0 | 0 | O | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Sitting: read, knit, sew, visiting, using computer (not at work) | ○ Yes ○ No | 0 | 0 | 0 | 0 | 0 | O | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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| | | | | |

QUASI STUDY Stress

| Date Form Completed | | | | | | | | | |
|---------------------|-----|---|------|--|--|--|--|--|--|
| Month / | Day | 1 | Year | | | | | | |
| / | | / | | | | | | | |

This next set of questions deal with things you may or may not have experienced in your life. Many of these may have caused you to become emotionally stressed or upset.

| EVENT | | this ent rred? | How many times has this happened to you ? | How stressed or upset were you the FIRST time this happened to you? | | | |
|--|----|----------------------|--|---|------|-------|--|
| | No | Yes | Number of times | None | Some | A Lot | |
| 1. Has someone close to you died? | O | О | | O | О | Ο | |
| 2. Have you ever been divorced? | 0 | 0 | | 0 | 0 | 0 | |
| 3. Have you ever been separated? | 0 | O | | O | 0 | Ο | |
| Have you ever had a spouse, partner or boyfriend cheat on you? | 0 | 0 | | 0 | 0 | 0 | |
| Have you ever experienced an INCREASE in number of arguments with your spouse, partner or boyfriend? | 0 | O | | O | O | Ο | |
| 6. Have you ever been homeless? | 0 | 0 | | 0 | 0 | 0 | |
| 7. As an adult, have you ever had to move back in with your parents? | 0 | O | | O | O | Ο | |
| 8. Have you ever been arrested? | 0 | 0 | | 0 | 0 | 0 | |
| 9. Have you ever had a spouse or boyfriend who has been arrested while you lived together? | 0. | O | | Ο | Ο | 0 | |
| 10. Has a spouse, partner or boyfriend ever physically beaten you? | 0 | 0 | | 0 | 0 | 0 | |
| 11. Has a spouse, partner or boyfriend ever been verbally or emotionally abusive toward you? | 0 | 0 | | О | О | 0 | |
| 12. As an adult, have you ever been physically beaten by someone other than a spouse, partner or boyfriend? | 0 | 0 | | 0 | 0 | 0 | |
| 13. Have you ever been forced to have sex against your will? | 0 | 0 | | O | O | 0 | |

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These items address how much emotional support you feel that you have.

| y | eneral, how satisfied are ou with your personal ationships with your | Not Satisfied | Moderately Satisfied | Very Satisfied | Not Applicable |
|-----|--|------------------|-------------------------|-------------------|-------------------------|
| 14. | Spouse, partner or boyfriend | Ö | 0 | O | O No Spouse/ Partner |
| 15. | Relatives | 0 | 0 | 0 | O No Relatives |
| 16. | Friends | O | O | O | O Ro Friends |
| 17. | Children | 0 | 0 | 0 | O No Children |

Please respond as to how you feel these statements apply to you.

| STATEMENT | Not At All | Less Than Some | Some | More Than Some | Very Much |
|---|---------------|----------------------|------|----------------------|--------------|
| 18. In general, I feel I can count on support from friends, acquaintances and coworkers. | O | O | 0 | O | O |
| 19. I feel I can count on support from my family members. | 0 | 0 | 0 | 0 | 0 |
| 20. I feel I can count on support from members of my partner's family. | O | O | O | O | O |
| 21. I feel I can count on support from my partner. | 0 | 0 | 0 | 0 | 0 |
| 22. There is someone I can count on to help me feel better when I feel under stress. | О | O | 0 | O | 0 |
| 23. There is someone who accepts me totally including both my worst and best points. | 0 | 0 | 0 | 0 | 0 |
| 24. There is someone I can count on to care about me, regardless of what is happening to me. | 0 | O | O | O | O |
| 25. There is someone I can count on to help me feel better when I am feeling down-in-the-dumps. | 0 | 0 | 0 | 0 | 0 |
| 26. There is someone I can count on to console me when I am upset. | Ο | O | О | Ο | Ο |

|--|

QUASI STUDY Personal History

| Date Form Completed | | | | | | | | | |
|---------------------|-----|---|------|--|--|--|--|--|--|
| Month / | Day | 1 | Year | | | | | | |
| / | | 1 | | | | | | | |

- 1. Were you adopted?
 - O Yes, know about biological mother's pregnancy
 - O Yes, don't know about biological mother's pregnancy (go to question #17)
 - O No
 - Ounsure (go to question #17)
 - 2. How old was your mother when you were born?

 1 00
 2 00
 3 00
 4 00
 5 00
 3. Before you were born, did your mother
 - 3. Before you were born, did your mother have any pregnancies?

9 00

8

4. How many of your mother's pregnancies before you were . . . ?

| Live Single Births | Live Multiple Births (1 set of twins=2, 1 set of triplets=3, etc.) | Stillbirths (born after 20 weeks of pregnancy) |
|--------------------|--|--|
| | | |
| 0 00 | 0 00 | 0 00 |
| 1 00 | 1 00 | 1 00 |
| 2 00 | 2 00 | 2 00 |
| 3 00 | 3 🔾 | 3 00 |
| 4 00 | 4 00 | 4 00 |
| 5 00 | 5 🔾 | 5 00 |
| 6 00 | 6 🔘 | 6 00 |
| 7 00 | 7 00 | 7 00 |
| 8 00 | 8 🔾 🔾 | 8 00 |
| 9 00 | 9 00 | 9 00 |

| 5. | Were you a twin or multiple birth? | | | | | | | | | | |
|-----|------------------------------------|---------------------------------------|-------------------------------|------------------------------|---------------------------------------|---|----------------------|---|---|--|--|
| | ΟYe | ○ Yes ○ No (go to question #8) | | | | | | | | | |
| | 6. | Wer | e you a | nd yo | ur twin i | dentical? | | | | | |
| | | O Y | ′es (go t | o ques | stion #8) | ○ No | | | | | |
| | | 7. | Was | you tv | vin fema | le? | | | | | |
| | | | ○Ye | s (|) No | | | | | | |
| 8. | (If yo #11. ounc | u are If you es, ple ving "l | sure of the are not ease give | he exa sure o e your l | ct weight f the exac pest estin | you were , go to que et pounds a nate, mark tinue to qu | estion and the | Pounds 0 0 0 1 0 0 2 0 0 3 0 0 4 0 0 5 0 0 6 0 0 7 0 0 8 0 0 9 0 0 | Ounces 0 0 0 1 0 0 2 0 0 3 0 0 4 0 0 5 0 0 7 0 0 8 0 0 9 0 0 | | |
| | 9. | | | | | 5 1/2 poui | | | | | |
| | | ΟY | es (go t | o ques | tion #11 |) ONo | () Un: | sure | | | |
| | | 10. | Did y ○ Ye | | | ounds or i | | | | | |
| 11. | Did y | our n | nother s | smoke | cigaret | tes durinç | g her pre | gnancy with y | you? | | |
| | ○ Ye | es (| ○ No | () Uı | nsure | | | | | | |
| 12. | _ | | | | | during he | r pregnaı | ncy with you? | ? | | |
| | ∫Y€ | ;S (| ○ No | U UI | nsure | | | | | | |
| 13. | Did y | our n | nother t | ake D | ES while | she was | pregnar | nt with you? | | | |
| | \bigcirc Ye | es | ○ No | \bigcirc U | nsure | | | | | | |

| | 14. | Did your mother take hormones or hormone medication other than DES while she was pregnant with you? |
|-----|------|--|
| | | |
| | 15. | Is your mother still living? |
| | | ○ Yes ○ No (go to question #17) |
| | | 16. Would you be willing to contact your mother to verify the information about her pregnancy with you?○ Yes ○ No |
| | | |
| 17. | Have | you ever been pregnant? |
| | ○ Ye | es ONo (go to question #21) |
| | 18. | How many times were you pregnant? 0 00 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 9 00 |
| | 19. | How old were you during your first pregnancy? O OO 1 OO 2 OO 3 OO 4 OO 5 OO 6 OO 7 OO 8 OO 9 OO |

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20. Please fill in the following chart regarding your pregnancies.

| Pregnancy Result | How many pregnancies ended with this result? | | | | | Did you breast feed any of these babies? If so, give the length of time in months you breast fed. | | | |
|---------------------------------------|--|--|--------------------------|-------------|--|---|---|--|--|
| Live single births | 01 07 | | ○3 ○9 | O 4 O 10 | O 5 O 11 | 06 012 | | | |
| Multiple births, at least one live | 01 07 | O2 O8 | 03 09 | 04 010 | 05 011 | 06 012 | O No O less than 6 O 6 to 12 O 12 to 18 O 18 or more | | |
| Multiple births, none living | 01 07 | er i Spiloto i S | ○ 3 ○ 9 | O 4 O 10 | 05 011 | 06 012 | | | |
| Stillbirths | 01 07 | 02 08 | 03 09 | 04 010 | 05 011 | 06 012 | | | |
| Miscarriages | 01 07 | Solid States of | G 81 1 | 0 4 0 10 | ○ 5 ○ 11 | 06 012 | | | |
| Induced abortions | 01 07 | 02 08 | 03 09 | 0 4 0 10 | 05 011 | 06 012 | | | |
| Ectopic or tubal | 01 | O 2 O 8 | | O 4 O 10 | Maria de la compansión de | O 6 O 12 | | | |

| 21 | How old were you when | you had ve | our first m | enstrual : | period? |
|-----|------------------------|------------|-------------|------------|---------|
| 21. | How old were you wrien | vou nau v | our morni | ciisti aai | perioa. |

| | | Years |
|--------|---------|-------|
| 0 | 00 | |
| 1 2 | 00 | |
| 3 | 00 | |
| 4 | 00 | |
| 5 6 | OO | |
| 7 | | |
| 8 | 00 | |
| 9 | \circ | |

22. What is or was your usual cycle length, that is from the beginning of one period to the beginning of the next one?

Days

Days

Days

Days

23. Did you ever miss your period for 3 or more consecutive months, for any reason other than pregnancy or breast feeding?

○ Yes ○ No (go to question #25)

24. If yes, how many months? Months

0 00

2 00

4 00

6 00

7 00

25. Have you had a period within the last year?

○ Yes ○ No (go to question #27)

26. In the last year, how many times have you had what you consider to be a regular period?

O 1

 \bigcirc 2

3

O4

O 5

6

O7

08

9

O 10

O11

○ 12 or more

| 27. | 7. Before today, did a doctor ever tell you that you had any of the following conditions? If so, please give your age when first told. | | | | | | |
|-----------|--|-------|--------------|---|-------|--|--|
| a. | Diabetes, high blood sugar | ○ No | ○Yes | | Years | | |
| b. | Inflammatory bowel disease, colitis or Crohn's disease | ○ No | ○Yes | | Years | | |
| C. | Colon or rectal polyps | ○ No | ○ Yes | | Years | | |
| d. | Stomach or duodenal ulcers | ○ No | ○ Yes | | Years | | |
| е. | Chronic lung diseases, bronchitis or emphysema | ○ No | ○ Yes | | Years | | |
| f. | Congestive heart failure | ○ No | ○Yes | | Years | | |
| g. | Heart attack, coronary or myocardial infarction | () No | ○Yes | | Years | | |
| h. | Chest pain or angina | ○ No | ○ Yes | | Years | | |
| | High blood cholesterol requiring medication | ○ No | ○ Yes | * | Years | | |
| j. | High blood pressure (hypertension) not during pregnancy | ○ No | ○Yes | | Years | | |
| k. | Stroke or brain hemorrhage | ○ No | ○ Yes | | Years | | |
| I. | Liver disease or cirrhosis | ○ No | ○Yes | | Years | | |
| m. | . Hepatitis | ○ No | ○ Yes | | Years | | |
| n. | Pancreatitis | ○ No | ○Yes | | Years | | |
| 0. | Kidney or bladder stones | ○ No | ○ Yes | | Years | | |
| p. | Chronic kidney disease or failure | ○ No | ○ Yes | | Years | | |
| q. | Gall stones or gall bladder disease | ○ No | ○ Yes | | Years | | |
| r. | Thyroid disease | ○ No | ○ Yes | | Years | | |
| s. | Osteoporosis (weak, thin or brittle bones) | ○ No | ○ Yes | | Years | | |
| t. | Depression or anxiety requiring medication | ○ No | ○ Yes | | Years | | |

| 28. | Have | you had | a hyste | rectom | ıy? | | | | | | |
|-----|--------------|----------------------|------------|------------------|---------------------------|---------------------------|-------------------|--|---|---|---|
| | ○ No | (go to qu | estion# | 30) |) Yes | | | | Da | | _ |
| | 29. | On wha | it date d | id you | have a l | nystered | tomy? | Mon 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | th / D / C O O O O O O O O O O O O | ay / Y | |
| 30. | | you had (go to qu | | _ | omy (ha) Yes | d your c | ovaries I | remove | d)? | | |
| | 31. | How m | any ovai | ries we | re remo | ved? | | | | | |
| | | O 1 | O 2 | | | | | | Da | ate | |
| | 32. | On wha | at date d | id you | have ar | oophei | rectomy | 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | hth / [] / [0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | Day / \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | Year OOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOOO |
| 33. | How | many si | sters do | you ha | ave? Pl | ease inc | lude on | ly bloo | d-relate | ed sister | s with the same |
| | O 0 | nts, and | | | Ceased | | 6 | 0 7 | 08 | 9 | ○ 10 or more |
| 34. | How with | many sis | sters do | es you s, and | r <u>mothe</u> include | <u>r</u> have? any dec | Please eased s | includ sisters. | e only b | olood-re | lated sisters |
| | \bigcirc 0 | O 1 | <u>2</u> | ○3 | O 4 | 5 | ○ 6 | 7 | 8 🔾 | 9 | ○ 10 or more |

| | | | | |
|------|------|------|------|---|
| | | | | - |
| ID I | | | | |
| | | Ì | | |
| | | | | |

10 or more

08 09

| 35. | How many sisters does your father have? Please include only blood-related sisters with |
|-----|--|
| | the same parents, and include any deceased sisters. |

00 01 02 03 04 05 06 07

36. Is there a history of female breast cancer in your family?

○ Yes ○ No (go to question #38)

37. If yes, please complete the charts below.

| RELATIVE | | tive had breast as it first diagno | If the relative had breast cancer, in how many breasts? | | |
|--------------------|---------------------|---------------------------------------|---|---------------|----------------|
| RELATIVE | Before Menopause | After Menopause | Not Sure When | One Breast | Two Breasts |
| Mother | O | O | O | 0 | O |
| Father's Mother | 0 | 0 | 0 | 0 | 0 |
| Mother's Mother | 0 | 0 | O | Ô | O |

| | How many relatives | | | | | | | | | | | |
|----------|-------------------------------------|---|---|---------------------------------------|---|--|--|--|--|--|--|--|
| RELATIVE | Had breast cancer before menopause? | Had breast cancer after menopause? | Had breast cancer but not sure when | Had breast cancer in one breast | Had breast cancer in both breasts | | | | | | | |
| Sisters | 04 05 06 07 08 09 | | 04 05 06 | 04 05 06 | 04 05 06 | | | | | | | |
| Aunts | | 01 02 03 04 05 06 07 08 09 010 or more | | | _ | | | | | | | |

| 20 | Have any of your | close male relatives | ever had | breast | cancer? |
|------------|------------------|----------------------|----------|--------|----------|
| 38. | Have any of your | Close male relatives | evel nau | Dicasi | Cancer : |

○ Yes ○ No (go to question #40) ○ Don't Know (go to question #40)

39. If yes, what was their relationship to you?

○ Father ○ Grandfather ○ Brother ○ Uncle

| 40. | Did y | | cigar o | r pipe a day for six months or longer? |
|-----|-------|---|-----------|--|
| | 41. | How old were you when you started smoking? | 42. | If you no longer smoke, how old were you when you stopped smoking on a regular basis? |
| | | Years | | Years |
| | | 0 00 | | 0 00 |
| | | 1 <u>00</u> 2 <u>00</u> | | 1 00 2 00 |
| | | 3 <u>00</u> 4 <u>00</u> | | 3 <u>0</u> 0 4 <u>0</u> 0 |
| | | 5 <u>00</u> 6 <u>00</u> | | 5 <u>0</u> 0 6 <u>0</u> 0 |
| | | 7 <u>00</u> 8 <u>00</u> | | 7 <u>00</u> 8 <u>00</u> |
| | | 9 00 | | 9 00 |
| | 43. | What did or do you usually smoke? ○ Cigarette ○ Cigar ○ Pipe | (Select | only one.) |
| | 44. | Have you smoked at least one cigare ○ Yes ○ No | ette, cig | par or pipe per week for the past year? |
| | 45. | On the average weekday (Monday-Friday), how many cigarettes, cigars or pipefuls of tobacco have you smoked (or did you smoke if you have quit) per day? | 46. | On the average weekend (Saturday, Sunday), how many cigarettes, cigars or pipefuls of tobacco have you smoked (or did you smoke if you have quit) per day? |
| | | cigarettes, cigars or pipefuls of tobacco | | cigarettes, cigars or pipefuls of tobacco |
| | | 1 00 | | 1 OO 2 OO |
| | | 3 00 | | 3 OO 4 OO |
| | | 5 🔘 | | 5 00 |
| | | 7 00 | | 7 00 8 00 |
| | | 8 OO 9 OO | | 9 00 |

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|----|--|--|--|--|
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| 47. | What is the tallest you have ever been without shoes? | 0 (1 2 (2 3 (4 5 (6 7 (7 8 (9 | Feet 0 0 1 0 3 4 0 6 7 8 0 9 | Inche | es 48. | | How old were you when you first reached this height? | 0 1 2 3 4 5 6 7 8 9 | Years OO |
|-----|---|--|-------------------------------|-------|---------------|--|--|--|--------------------------------------|
|-----|---|--|-------------------------------|-------|---------------|--|--|--|--------------------------------------|

49. How much did you weigh at the following times when you were not pregnant or nursing?

| Age 18 Years | Age 30 Years | Age 50 Years | 5 Years Ago |
|--|--|--|--|
| Pounds | Pounds | Pounds | Pounds |
| 0 000 1 000 2 000 3 000 4 000 5 000 6 000 7 000 8 000 9 000 | 0 000 1 000 2 000 3 000 4 000 5 000 6 000 7 000 8 000 9 000 | 0 000 1 000 2 000 3 000 4 000 5 000 6 000 7 000 8 000 9 000 | 0 000 1 000 2 000 3 000 4 000 5 000 6 000 7 000 8 000 9 000 |

- 50. Before today, what is the most you have ever weighed when you were not pregnant, nursing, or in the six months after pregnancy or nursing?
 - Pounds

 0 000
 1 000
 2 000
 3 000
 4 000
 5 000
 6 000
 7 000
 8 000

51. How old were you when you first reached your maximum adult weight?

| | Years |
|---|-------|
| 0 1 2 3 4 5 6 7 8 | |
| 9 | 00 |

|--|

| 52. | טום you ever | take birtii co | ontroi piiis | s for a consecu | live moi | itiis oi iii | ore: | | |
|--|----------------------------|---|--|--|---------------------------------------|---|---|------------------------------|------------------|
| | ○Yes ○N | No | | | | | | | |
| 53. | Have you see last three mo | nths? | or attend | led nutrition (we | eight los | ss or othe | r types |) class | es in the |
| | | | Religi | on ID Number L | ist | | | | |
| 03 = M 04 = L 05 = P 06 = R 07 = C | | Judaism: W your ancest 09 = Orthodox 10 = Conserva 11 = Reform 12 = Reconstr 13 = Ashkena 14 = Sephard 15 = Other | ative cuctionist zi | <u>Islam</u> 16 = Sunni 17 = Shi'ite 18 = Other | 19 20 21 22 23 24 | ther = Buddhist = Hindu = Shinto = Wiccan = Santeria, = Pagan or religion = Atheist = Agnostic | | | |
| 54. | What was the | religion or | spiritual to | radition <u>in whic</u> 5. Enter the R | <u>ch you w</u> eligion l | vere raise ID Numbe | d as a c | <u>:hild,</u> if the list | f any? above. |
| | ID Numb | er: | 0 00 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 9 00 | 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 | 4 O 5 O 6 O 7 O 8 O | 0 0 1 2 3 4 5 6 7 8 9 | 000000000000000000000000000000000000000 | | |
| 55. | What is your that apply up | present religion to 5. Enter | gion or sp the Religi | oiritual affiliation ion ID Number t | n, if any from the | ? Please list abov | mentio e. | n all | |
| | ID Numb | | 0 00 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 9 00 | 0 00 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 | 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | 0 0 1 2 3 0 4 5 6 7 8 | 000000000000000000000000000000000000000 | | ur. |

| 56. | How often do you attend religious or spiritual services at a church, synagogue, mosque, or other religious or spiritual meeting place? | | | | | |
|-----|--|-----------------------------------|---|--|--|--|
| | O Ne | ever (go to question #58) | O 2-6 times per week | | | |
| | O 1 | time per month | ○ 1 time per day | | | |
| | O 2- | 3 times per month | ○ 2+ times per day | | | |
| | O 1 | time per week | | | | |
| | 57. | For how many years have yo | u attended religious or spiritual services? | | | |
| | | ◯ 1 year | ○ 11-20 years | | | |
| | | ◯ 2-5 years | ○ 21-30 years | | | |
| | | ○ 6-10 years | ○ 30+ years | | | |
| 58. | Besides formal group-based spiritual services, how often do you engage in meditation, prayer, self-hypnosis, or other spiritual practices (such as visualization)? | | | | | |
| | O Never (go to question #60) | | O 2-6 times per week | | | |
| | ○ 1 time per month | | ○ 1 time per day | | | |
| | ○ 2-3 times per month | | ○ 2+ times per day | | | |
| | ○ 1 time per week | | | | | |
| | 59. | For how many years have you | engaged in the activities in question #58? | | | |
| | | ○1 year | | | | |
| | | ○ 2-5 years | | | | |
| | | ○ 6-10 years | ◯ 30+ years | | | |
| 60. | Whic | h of these spiritual practices ha | ave you done the most? | | | |
| | ○ Relaxation exercises | | | | | |
| | ○Me | ditation | | | | |
| | ○ Sel | lf-hypnosis | | | | |
| | ○ Ima | agery or visualization | | | | |
| | ○ Pra | ayer | | | | |

| I consider myself to be a spiritual person | n. | | |
|--|--|---|--|
| O Strongly Disagree | ○ Agree | ee | |
| ○ Disagree | ○ Stro | ngly Agree | |
| O Neither Agree Nor Disagree | | | |
| stions #62-73 refer to your usual sleeping hat s to the time you are actually asleep and doe as when reading. | oits over the s not inclu | ne past year. Please note t ide any other time you may | hat sleeping spend in bed |
| On a typical weekday (Monday-Friday), what time do you usually attempt to fall asleep? Note that this may not be the same time | 63. | On a typical weekday (Monday-Friday), what ti usually wake-up? | me do you |
| | | | ○AM |
| 0 00 00 OPM | | 0 00 00 | ○PM |
| 3 00 00 | | 3 00 00 | |
| 4 00 00 5 00 00 | | 4 <u>00 00</u> 5 00 00 | |
| | | 6 00 00 | |
| 8 000 000 | | 8 00 00 | |
| 9 00 00 | | 9 00 00 | |
| On a typical weekend (Saturday, Sunday), what time do you usually attempt to fall asleep? Note that this may not be the same time you go to bed. | 65. | On a typical weekend (Sunday), what time do usually wake-up? | |
| : | | | \bigcirc AM |
| 0 00 00 OPM | | 0 00 00 | ○PM |
| 2 00 00 | | 2 00 00 | |
| 3 00 00 | | 3 00 00 4 00 00 | |
| 5 00 00 6 00 00 | | 5 OO OO 6 OO OO | |
| | Ostrongly Disagree ○ Disagree ○ Neither Agree Nor Disagree Stothe time you are actually asleep and doe as when reading. On a typical weekday (Monday-Friday), what time do you usually attempt to fall asleep? Note that this may not be the same time you go to bed. □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ | O Disagree O Neither Agree Nor Disagree Stions #62-73 refer to your usual sleeping habits over the stook to the time you are actually asleep and does not include as when reading. On a typical weekday (Monday-Friday), what time do you usually attempt to fall asleep? Note that this may not be the same time you go to bed. On a typical weekend O O O O PM O O O O O O O O O O O O O O O O O O O | O Strongly Disagree O Disagree O Neither Agree Nor Disagree Strongly Agree O Neither Agree Nor Disagree Strongly Agree O To a typical weekday (Monday-Friday), what time you go to bed. O Sunday, what time do you usually attempt to fall asleep? Note that this may not be the same time you go to bed. On a typical weekend (Saturday, Sunday), what time do you usually attempt to fall asleep? Note that this may not be the same time you go to bed. On a typical weekend (Saturday, Sunday), what time do usually wake-up? |

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| 66. After falling asleep, how many times do you usually wake up during the ni | | | | | | | | e nig | ht? | |
|---|------|---|------------|------------|-----------|---|--|--|--|------|
| | 00(| go to question #70) | O 1 | O 2 | ○3 | 4 | ○ 5 or more | | | |
| | 67. | If you wake up du ○ Yes ○ No | ring the | night, d | do you ι | ısually t | urn on the lights | s? | | |
| | 68. | If you wake up du | ring the | night, I | now Ion | g are yo | u usually awake | 0 1 2 3 4 5 6 7 8 9 | Minu OO OO OO OO OO OO OO OO OO | ites |
| 69. Why do you usually wake up? Select the most common reason. | | | | | | | | | | |
| | | ○ To use bathroom○ Noise○ Bedpartner wake | | р | (| Child care or care for another personUncomfortable or in painJust wake up (no obvious reason) | | | | |
| 70. | Do y | ou sleep more in or | ie seasc | on than | another | ? | | | 4 | |
| | ○ Ye | es ONo (go to qu | estion # | 74) | | | | | | |
| | 71. | If you sleep more what is the seaso your longest and | nal diffe | rence i | n sleep l | | Hour 0 00 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 | s 0 1 2 3 4 5 6 7 8 9 | Minu 00 00 00 00 00 00 00 | ıtes |

| | 72. | If you sleep more in the most? | one season th | an another, in whic | ch seas | son do you sleep |
|-----|------|--|--|---|---------|--|
| | | ○ Summer ○ Fall | ○ Winter | ○ Spring | | |
| | 73. | If you sleep more in the least? | one season th | an another, in whic | ch seas | son do you sleep |
| | | ○ Summer ○ Fall | ○ Winter | ○ Spring | | |
| 74. | | ing, accupressure or s | | | | such as yoga, tai chi, touch or healing |
| | ○ Ye | es ONo (go to ques | tion #79) | | | |
| | 75. | How long was each session of exercise? | do | w often did you these exercise ssions? | 77. | For how many years did you regularly do these exercises? |
| | | Minutes | | Times Per () Wee | ek | Years |
| | | 0 OO 1 OO 2 OO 3 OO 4 OO 5 OO 6 OO 7 OO 8 OO 9 OO | 0 OC 1 OC 2 OC 3 OC 5 OC 6 OC 7 OC 8 OC | Year () Year () () () () () () () () () () () () () | | 0 00 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 9 00 |
| | 78. | Which form of the e | exercises in qu | estion #74 have yo | u done | e the most? |
| | | <u></u> Yoga | | | | |
| | | ◯ Tai Chi | | | | · |
| | | ○ Qi Qong | | | | |
| | | O Accupressure or Sh | niatsu | | | |
| | | ○ Self-massage | | | | |
| | | O Reiki, Therapeutic | Touch or Healir | ng Touch | | |

| 79. | How many years have you kept the following pets? (Enter "00" if you never have kept |
|-----|---|
| | such pets.) |

| Dogs | Cats | Birds | Other |
|-------|-------|-------|-------|
| Years | Years | Years | Years |
| 0 00 | 0 00 | 0 00 | 0 00 |
| 1 00 | 1 00 | 1 00 | 1 00 |
| 2 00 | 2 00 | 2 00 | 2 00 |
| 3 🔾 | 3 🔾 | 3 🔾 | 3 00 |
| 4 00 | 4 00 | 4 00 | 4 00 |
| 5 00 | 5 🔾 | 5 🔾 | 5 🔾 |
| 6 00 | 6 00 | 6 00 | 6 00 |
| 7 00 | 7 00 | 7 00 | 7 00 |
| 8 00 | 8 00 | 8 00 | 8 00 |
| 9 00 | 9 00 | 9 00 | 9 🔾 |

- 80. In the past year was there a period of two weeks during which you felt depressed or down most of the day nearly every day?
- 81. Was there a time in the past year when you were uninterested in most things or unable to enjoy things you normally enjoy?
 - ○Yes ○No
- 82. Are you currently being treated for nervous, emotional, or psychological problems in counseling or psychotherapy?
 - Yes No (go to question #85)
 - 83. Please describe the kind of nervous, emotional or psychological problems for which you are being treated in counseling or psychotherapy.

84. How often do you attend therapy?

Times per \(\rightarrow \text{Week} \)

- 0 00
- Month
- 2 00
- 3 ŎŎ
- 4 00
- 5 00
- 6 00
- 3 00
- 9 ÖC

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| | | | | |

85. Please fill in the table below considering drugs you have taken within the last 5 years for headaches, arthritis, swelling and any other aches and pains. Only include medications used for at least 3 consecutive months.

| | tak | you e the ug? | How often did you take the drug? (Select only one.) | | | | | For what period of time did you take the drug? (Select only one.) | | | | |
|--|-----|---------------------|---|--------------------|-------------------|-------------------|-------------------|---|---------------|---------------|---------------|---------------|
| Drug | Yes | No | 1 Day per Month | 2-3 Days per Month | 1-2 Days per Week | 3-4 Days per Week | 5-7 Days per Week | 3 Months to 1 Year | Up to 2 Years | Up to 3 Years | Up to 4 Years | Up to 5 Years |
| Aspirin: Anacin, Bufferin, Bayer, Ecotrin | Ó | O | O | O | 0 | 0 | 0 | 0 | O | 0 | O | Ο |
| Ibuprofen: Motrin, Advil, Nuprin, Medipren, Rufen | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Acetaminophen: Excedrin, Tylenol, Panadol, Midrin, Darvocet-N, Feverall, Lurlene | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | O | 0 | 0 |
| Indomethacin: Indomet, Indocin | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Naproxen: Alleve, Naprosyn, Anaprox | | 0 | 0 | 0 | 0 | 0 | | 0 | 0 | O | Ο | O |
| Ketoprofen: Orudis, Actron | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Other Pain Reliever: piroxicam, feldene, sulindac, lodine, ketolac, fenoprofen, nalfon, meclomen, ponstel, or any other | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Ο | O | O | 0 |
| Tamoxifen | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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DIRECTIONS: Listed below are some of the reactions people have to certain feelings or emotions. Read through the items on each list and, by choosing the appropriate answer, indicate the way you generally react.

| REACTIONS | Almost Never | Sometimes | Often | Almost Always |
|---------------------------------------|-----------------|-----------|-------|------------------|
| When I feel angry (very annoyed) | | | | |
| A. I keep quiet. | 0 | 0 | 0 | 0 |
| B. I refuse to argue or say anything. | 0 | Ο | · O | O |
| C. I bottle it up. | 0 | 0 | 0 | 0 |
| D. I say what I feel. | 0 | 0 | O | O |
| E. I avoid making a scene. | 0 | 0 | 0 | 0 |
| F. I smother my feelings. | 0 | 0 | O | O |
| G. I hide my annoyance. | 0 | 0 | 0 | 0 |
| When I feel anxious (worried) | | | | |
| H. I let others see how I feel. | 0 | 0 | 0 | 0 |
| I. I keep quiet. | 0 | 0 | O | O |
| J. I refuse to say anything about it. | 0 | 0 | 0 | 0 |
| K. I tell others about it. | 0 | Ο | O | 0 |
| L. I say what I feel. | 0 | 0 | 0 | 0 |
| M. I bottle it up. | 0 | 0 | O | O |
| N. I smother my feelings. | 0 | 0 | 0 | 0 |



| REACTIONS | Almost Never | Sometimes | Often | Almost Always |
|--|-----------------|-----------|-------|------------------|
| When I feel unhappy (miserable) | | | | |
| O. I refuse to say anything about it. | 0 | 0 | 0 | 0 |
| P. I hide my unhappiness. | O | Ο | 0 | O |
| Q. I put on a bold face. | 0 | 0 | 0 | 0 |
| R. I keep quiet. | O | 0 | O | O |
| S. I let others see how I feel. | 0 | 0 | 0 | 0 |
| T. I smother my feelings. | 0 | 0 | O | O |
| U. I bottle it up. | 0 | 0 | 0 | 0 |
| | | | | |
| The frequency that I feel angry or annoyed. | 0 . | 0 | 0 | 0 |
| The frequency that I feel anxious or worried. | 0 | O | O | Ö |
| The frequency that I feel unhappy, depressed or miserable. | 0 | 0 | 0 | 0 |

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QUASI STUDY Rosenberg

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DIRECTIONS: Below is a list of statements with which you may agree or disagree. Please indicate whether you agree or disagree with each statement by marking one response to the right of each statement. Note that responses include Strongly Disagree, Disagree, Agree, and Strongly Agree.

| | STATEMENTS | Strongly Disagree | Disagree | Agree | Strongly Agree |
|------|---|----------------------|----------|-------|-------------------|
| 1. = | I feel that I'm a person of worth, at least on an equal basis with others. | 0 | O | O | O |
| 2. | I feel that I have a number of good qualities. | 0 | 0 | 0 | 0 |
| 3. | All in all, I am inclined to feel that I am a failure. | O | Ο | Ο | O |
| 4. | I am able to do things as well as most other people. | 0 | 0 | 0 | 0 |
| 5. | I feel I do not have much to be proud of. | O | 0 | Ο | O |
| 6. | I take a positive attitude toward myself. | 0 | 0 | 0 | 0 |
| 7. | On the whole, I am satisfied with myself. | O | O | Ο | O |
| 8. | I wish I could have more respect for myself. | 0 | 0 | 0 | 0 |
| 9. | I certainly feel useless at times. | O | 0 | Ο | O |
| 10. | At times I think I am no good at all. | 0 | 0 | 0 | 0 |

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QUASI STUDY SF-36[™] Health Survey

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| | / | | / | | | |

DIRECTIONS: Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

EXAMPLE

1.

This is for your review. Do not answer this question. The questionnaire begins with the section Your Health in General below.

For each question you will be asked to fill in a bubble in each line.

1. How strongly do you agree or disagree with each of the following statements?

| | | Strongly Agree | Agree | Uncertain | Disagree | Strongly Disagree |
|----|-----------------------------|-------------------|-------|-----------|----------|----------------------|
| a. | I enjoy listening to music. | 0 | • | 0 | 0 | 0 |
| b. | I enjoy reading magazines. | • | 0 | 0 | 0 | 0 |

Please begin answering the questions now.

| | Your H | ealth in General | | |
|----------------|----------------------|------------------|------|------|
| In general, wo | uld you say your hea | alth is: | | |
| Excellent | Very good | Good | Fair | Poor |
| 0 | 0 | 0 | 0 | 0 |

2. Compared to one year ago, how would you rate your health in general now?

| Much better now than | Somewhat better now than one | About the same as one | Somewhat worse now than one | now than one |
|----------------------|---------------------------------|-----------------------|-----------------------------|--------------|
| one year ago | year ago | year ago | year ago | year ago |
| 0 | 0 | 0 | 0 | 0 |

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| | | | | |

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

| | ACTIVITIES | Yes, limited a lot | Yes, limited a little | No, not limited at all |
|-----------|--|--------------------------|-----------------------------|------------------------------|
| a. | Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports | O | О | O |
| b. | Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf | 0 | 0 | 0 |
| c. | Lifting or carrying groceries | Ó | Ο | O |
| d. | Climbing several flights of stairs | 0 | 0 | 0 |
| e. | Climbing <i>on</i> e flight of stairs | O | O | O |
| f. | Bending, kneeling or stooping | 0 | 0 | 0 |
| g. | Walking <i>more than a mil</i> e | O | Ö | O |
| h. | Walking several blocks | 0 | 0 | 0 |
| i. | Walking o <i>ne block</i> | O | Ο | O |
| j. | Bathing or dressing yourself | 0 | 0 | 0 |

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

| | PROBLEMS | Yes | No |
|-----------|--|-----|----|
| a. | Cut down on the <i>amount of time</i> you spent on work or other activities | O | O |
| b. | Accomplished less than you would like | 0 | 0 |
| c. | Were limited in the <i>kind</i> of work or other activities | 0 | Ο |
| d. | Had difficulty performing the work or other activities (for example, it took extra time) | 0 | 0 |

| | | | | |
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5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

| | PROBLEMS | Yes | No |
|----|---|-----|----|
| a. | Cut down on the <i>amount of time</i> you spent on work or other activities | O | O |
| b. | Accomplished less than you would like | 0 | 0 |
| C. | Didn't do work or other activities as <i>carefully</i> as usual | (O) | О |

| 6. | During the past 4 weeks, to what extent has your physical health or emotional problem interfered with your normal social activities with family, friends, neighbors, or groups? |
|----|---|
| | interiered with your normal social activities with family, monae, norganized, |

| Not at all | Slightly | Moderately | Quite a bit | Extremely |
|------------|---------------------|---------------------|-------------|-----------|
| | libr nain hava yayı | had during the nast | 4 weeks? | |

7. How much bodily pain have you had during the past 4 weeks?

| None | Very mild | Mild | Moderate | Severe | Very severe |
|---------|-----------|------|----------|--------|-------------|
| \circ | Ó | 0 | 0 | 0 | 0 |
| | | | | | |

8. During the past 4 weeks, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

| Not at all | A little bit | Moderately | Quite a bit | Extremely |
|------------|--------------|------------|-------------|-----------|
| 0 | 0 | 0 | 0 | 0 |

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks . . .

| | | All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | None of the time |
|----|--|-----------------------|------------------------|------------------------------|------------------------|----------------------------|------------------------|
| a. | did you feel full of pep? | 0 | 0 | O | O | Ο | Ō |
| b. | have you been a very nervous person? | 0 | 0 | 0 | 0 | 0 | 0 |
| C. | have you felt so down in the dumps nothing could cheer you up? | 0 | 0 | 0 | Ο | 0 | Ô |

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| | i | | | |

9. (Continued) How much of the time during the past 4 weeks . . .

| | | All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | None of the time |
|----|--|-----------------------|------------------------|------------------------------|------------------------|----------------------------|------------------------|
| d. | have you felt calm and peaceful? | Ο | O | Ο | O | O | O |
| e. | did you have a lot of energy? | 0 | 0 | 0 | 0 | 0 | 0 |
| | have you felt down- hearted and blue? | Ο | 0 | 0 | · O | O | O |
| g. | did you feel worn out? | 0 | 0 | 0 | 0 | 0 | 0 |
| h. | have you been a happy person? | O | 0 | 0 | 0 | 0 | O |
| i. | did you feel tired? | 0 | 0 | 0 | 0 | 0 | 0 |

10. During the past 4 weeks, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

| All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|-----------------|------------------|------------------|----------------------|------------------|
| \cap | \cap | \circ | 0 | 0 |

11. How TRUE or FALSE is each of the following statements for you?

| | STATEMENT | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|----|---|-----------------|----------------|---------------|-----------------|------------------|
| a. | I seem to get sick a little easier than other people. | Ο | O | O | Ö | Ο |
| b. | i am as healthy as anybody i know. | 0 | 0 | 0 | 0 | 0 |
| C. | I expect my health to get worse. | Ο | Ó | O | Ö | O |
| d. | My health is excellent. | 0 | 0 | 0 | 0 | 0 |

Principal Investigators: James R. Hebert, Sc.D. Army Award: DAMD17-99-1-9279

Appendix 1
Assessment Instruments

| NAME:Vegetable and Fruit Questionnaire | | | | | |
|---|---|---|---|--------------------|--------------------|
| Please tell us how often you have eaten the spetoday. All portion sizes refer to cooked size us consumed the food and check off your usual pebroccoli three times (one cup at one sitting and | nless otherwise note ortion size as compa | ed. Please write in the arred to the Comparison | number of tim | nes that you | have |
| of occor times times (one cap at one saming and | Number of | Your Average | | | |
| | Times Eaten | Comparison Portion Size | Half this Size | | Twice this Size |
| Broccoli | 3 | <u>1/2</u> cup | | X | |
| | Number of | Comparison | | Your Average | |
| | Times Eaten | Portion Size | Half this Size | Equal to this Size | Twice this Size |
| Broccoli | | <u>1/2</u> cup | | | |
| Brussel Sprouts | | <u>4</u> sprouts | | | |
| Cabbage | | <u>1/2</u> cup | | | |
| Cauliflower | | <u>1/2</u> cup | | | |
| Chinese Cabbage | | <u>1/2</u> cup | | | |
| Collard Greens/Swiss Chard/Kohlrabi | | <u>1/2</u> cup | | | |
| Mustard Greens or Turnip Greens | | <u>1/2</u> cup | | | |
| Rutabaga / Turnips | | <u>1/2</u> cup | | | |
| Kale | | <u>1/2</u> cup | | | |
| Spinach | " | <u>1/2</u> cup | | | |
| Onions | | 1 sm or 1/4 cup | | | |
| Carrots | | 1 med or 1/2 cup | | | |
| Sweet Potatoes | <u></u> | 1/2 cup | | | |
| Soybeans - whole | | $\frac{1}{3/4}$ cup | | | |
| Soy milk 8oz. Glass | | 1-8oz Glass | | | |
| Tofu | | 3/4 cup | | | *** |
| | | $\frac{371}{1/2}$ cup | | | |
| Tempeh | | $\frac{1/2}{1/2}$ cup | | | |
| Broccoli Sprouts Alfalfa / Clover / Mung Bean / Soy Sprouts (raw) | - | $\frac{1/2}{1/2}$ cup | | | |
| | | $\frac{1/2}{1/2}$ cup | | | |
| Pinto Beans / Round Split Pea Pods | - | | | | |
| Fresh Green or Mung Beans | | <u>1/2</u> cup | | | |
| Garbanzo, Kidney Beans or Black-eyed, | | 1/2 | | | |
| Yellow Split or Chinese Peas | | $\frac{1/2}{1/2}$ cup | | | |
| Peas | - | $\frac{1/2}{1/2}$ cup | | | |
| Lentils / Dal | Barrey | $\frac{1/2}{1/4}$ cup | - | | |
| Seaweeds eaten dry (e.g., dulse, purple laver, nori) | | $\frac{1/4}{72}$ cup or | | | |
| | And Park Transport | 7" sq sheet | | | |
| Seaweeds eaten cooked or soaked | | 1 tbs or | | | |
| (e.g. arame, kombu, kelp) | | 2" sq piece | - | | |
| Apples | | $\frac{1 \text{ med or } 1/2}{1}$ cup | | - | |
| Bananas | | 1 medium | | | |
| Apricots | | 2 medium | | - | |
| Nectarines | | 1 med or 1/2 cup | *************************************** | | |
| Peaches | | 1 med or 1/2 cup | | | |
| Strawberries | | <u>1/2</u> cup | | | |
| Grapefruit | | 1/2 grapefruit | | | - |
| Lemon, squeezed | | 1/4 medium | | | |
| Orange | | 1 medium | | | |
| 100% Fruit Juice (any type) | | 1-8oz Glass | | | |
| Other Soy products not listed above, | | | | | |
| Please specify: | | Your portion size: | | | |
| * * | | = | | | |

Principal Investigators: James R. Hebert, Sc.D. Army Award: DAMD17-99-1-9279

Appendix 2
Recruitment and Consent

Dear «Title» «LastName»,

I am writing to tell you about an important research study at the University of South Carolina and the South Carolina Cancer Center that may be of interest to you, and I am inviting you to participate in this study. The Division of Population Studies at the Cancer Center has received funding to evaluate a dietary intervention designed to reduce the risk of some breast cancers. To complete the study, we are seeking women who are likely to be free of breast cancer. Therefore, the your hospital has given us permission to contact women that have recently received a breast screening mammogram.

We are conducting this study to determine if a dietary approach to breast cancer prevention is both acceptable to women and able to change the way hormones are broken-down. There is evidence that certain commonly known foods reduce the risk of developing breast cancer by altering the way a hormone called estradiol is degraded. We have developed a series of four classes, conducted by a registered dietitian, which are designed to introduce the health benefits of these specific foods. The course also provides preparation instruction and hands-on cooking opportunities in our teaching kitchen, and is free to study participants.

Once started, the study will require about twelve weeks. During this period of time, you would attend the four classes described above, provide four blood and urine samples, complete questionnaires, and accept twelve telephone calls from us to record the foods you have eaten. As a study participant, we will provide you, at your request, with summaries of your nutrient intake (e.g., fiber intake, fat intake, calorie intake, etc.) over the course of the study as well as the levels of measured hormones in your blood and urine. Other measurements will be collected, and we will discuss these measurements fully with you.

Enclosed you will find a <u>Consent Form</u> that summarizes the study procedures, as well as your rights, benefits, and risks with participation. Please read this Consent Form carefully and consider your ability to complete this study. In about a week the project manager, Jay Fowke, will be calling you to answer any questions you might have at this time. If you do not wish to be called, call the Division of Population Studies, SCCC, (803)434-1628, and leave a message that includes your name and a statement that you do not wish to participate.

Breast cancer prevention research relies on people to participate. With the success of this project, we hope that there will be more trials that might benefit women like you. We are excited about this study and look forward to your participation.

Sincerely,



| Review Date Approval Begins Approval Ends IRB Number | |
|--|--|
| June 16, 2000 June 16, 2000 June 15, 2001 #2000-78 | |

DATE:

September 21, 2000

TO:

James R. Hebert, Sc.D.

FROM:

Edward W. Catalano, M.D. Wittalo

Chair, Institutional Review Board (IRB)

SUBJECT:

Approval of New Protocol PHA IRB #2000-78 with Consent Form,

Biopsy Procedure Addendum and Sample Donation Form.

On June 16, 2000, the Institutional Review Board approved your protocol and consent form entitled:

PHA IRB #2000-78: Phase I Induction and Estrogen Metablosim in Women With and Without Breast Cancer and in Response to a dietary Intervention.

Approval is effective from June 16, 2000 until June 15, 2001. Unless the IRB has waived the requirement for documentation of informed consent, attached is the IRB approved consent/assent document(s) to be used when enrolling subjects. [Note, this dated consent is to be used as a master to copy for all patient consents. Subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp. A copy of the signed consent/assent form must be given to every study participant. A copy of the signed consent/assent form must be kept with your study records and in the patient's medical chart.] Upon request, you will be sent a clean copy of the current synopsis forms for renewal of the protocol, which must be completed and returned with a clean copy of the informed consent form, to the IRB at the Research Administration office, so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. No changes in the protocol or consent may be made without prior IRB approval. Any significant deviations on proposed changes must be reported to the IRB. If your study uses an IND, all administered dosages are to be documented in the patients' chart. Storage and administration of the study drug are to be documented as being in accordance with FDA requirements.

Please refer to the Palmetto Health Alliance <u>Investigator Brochure</u> regarding investigator responsibilities with respect to the ethical use of human subjects in research. If you have questions or need additional information, please contact the Research Administration office at 434-2884. Please forward a copy of any publication(s) resulting from this research to the IRB, for their information.

Palmetto Health Alliance

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

IRB#: 2000-78

TITLE: Phase I Induction and Estrogen Metabolism in Women With and Without Breast Cancer and in Response to a Dietary Intervention.

| DATE: | |
|-------|-------|
| | |
| | DATE: |

INVITATION TO TAKE PART AND INTRODUCTION:

You are invited to volunteer for a research study. You have been asked to be in this study because you previously donated a biological sample to breast cancer research at the South Carolina Cancer Center within Palmetto Richland Memorial Hospital (Columbia, S.C.).

PURPOSE OF THE RESEARCH:

The main purpose of this study is to determine if a 7-session dietary education program can help women incorporate into their diet certain foods that could alter levels of hormones thought to influence the risk of breast cancer. These foods are members of the *Brassica* genus. The most commonly consumed of these vegetables include cabbage, broccoli, cauliflower, and Brussels sprouts. The results of this study will help to develop dietary guidelines directed towards breast cancer prevention and altering the course of disease in women with breast cancer.

YOUR RIGHTS: It is important for you to know that:

- YOUR PARTICIPATION IS ENTIRELY VOLUNTARY.
- YOU MAY DECIDE NOT TO TAKE PART OR DECIDE TO QUIT THE STUDY AT ANY TIME.
- YOU WILL BE TOLD ABOUT ANY NEW INFORMATION OR CHANGES IN THE STUDY THAT MIGHT AFFECT YOUR PARTICIPATION.
- THE QUALITY OF CARE YOU RECEIVE AT THE HEALTH CENTER WILL NOT BE AFFECTED IN ANY WAY IF YOU DECIDE NOT TO PARTICIPATE OR IF YOU WITHDRAW FROM THE STUDY.

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| Subject's | Initials | Witness's | Initials |
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RANDOMIZATION:

Because it is not known whether changes in diet are effective in breast cancer prevention, not everyone in the study will be assigned to receive the dietary intervention. You will be assigned to one of two groups. One group will receive the dietary intervention, one group will not. This will make it possible for us to judge the effect of eating these vegetables in the fairest, most impartial way possible because the process of randomization ensures that the two groups of people (those receiving and those not receiving the intervention) are similar in other ways. The decision as to whether you receive the dietary intervention or not will be made by chance, like the flip of a coin, not by your doctor or based on your medical condition. You will have a 50% chance of receiving the intervention.

PROCEDURES:

Sub

You have previously visited the clinic, completed a questionnaire, and provided several samples. At that earlier visit, you might have donated a blood sample, a urine sample, and a portion of the breast biopsy tissue for breast cancer research, and you completed a questionnaire. A portion of these samples will be used for this research endeavor. We will use these samples to provide a baseline level of hormones that are thought to be important in modifying breast cancer risk.

This dietary study will last about three months, and 90 women will participate. If you are assigned to the dietary intervention, you will be asked to first meet with a study dietitian for a one-hour individual session. This session will be followed by 6 two-hour group sessions over a two-month period. These six classes will be held weekly. Approximately fifteen people will attend each class, and classes will be scheduled either on a weekday morning or evening. These sessions will include: 1. classroom presentations during which we will provide information about the vegetables – their chemical properties and their effects on health; 2. a group cooking experience in which you will be asked to learn about preparing the foods; and 3. a chance to eat what you have cooked with other women in the group.

You will be asked to add about four commonly known vegetables to your diet during the six weeks of the intervention. We will <u>not</u> be asking you to restrict your diet, or limit the other foods that you eat, in any way. The dietary intervention is not a weight loss program. You may eat anything that you wish to eat, but we ask that you also eat about two or three servings per day of the vegetables promoted in the intervention classes. These classes are designed to help you incorporate these vegetables into your normal meals.

We will ask to schedule a clinic visit with you near the end of the intervention. During this clinic visit, a blood sample will be drawn in the usual way, by inserting a needle into a vein in your arm. About 4 teaspoons (20 milliliters) of blood will be collected, and this blood will be used to determine if there are any changes in levels of the hormones that are thought to be important in modifying breast cancer risk. We will measure your weight and the circumference of your hips and waist. We will provide you with a small urine collection container to collect a first-morning urine sample, and this urine sample can be brought to the clinic when you have your blood drawn. It is important that this urine sample be collected before you eat that day. This urine sample will be used to determine if there are changes in the levels of certain female hormones (estrogens) that are excreted from your body in your urine. Additionally, urine samples will be used to determine the levels of chemicals that naturally exist in the foods you will be asked to eat. We also

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will obtain a fine-needle biopsy from the breast opposite to the one in which you had your original biopsy. Very little material is removed by biopsy, always less than a one-quarter of a thimble-full. This material will be used to determine levels of enzymes that are important in regulating levels of female hormones (estrogens). This will be done using a needle similar to that used for drawing blood. It will be done only once, at the very end of the study. You will be asked to complete several questionnaires about your present health, diet, medication use, and the current level of depression and anxiety. These questionnaires will be completed near the time of your clinic visit, and will require about one hour. After the end of the week of your last class, you will be advised that you may remove the intervention vegetables from your diet.

ALTERNATIVES:

You may choose not to take part in this study. If so, then you would not have to do any of the things listed above. This would in no way affect other aspects of your treatment or medical care.

RISKS AND INCONVENIENCES:

Drawing blood may hurt slightly, and you might have a black and blue mark. Occasionally a person may become dizzy or faint when blood is drawn and there is a slight possibility of infection or temporary nerve damage. There may be pain associated with the fine needle biopsy. This pain is usually short-lived (i.e., less than 12 hours), and well tolerated. Pain medication, for example Tylenol or Advil, can be taken to relieve this pain, and Tylenol capsules will be available at the time of the biopsy. Stronger pain medication may be prescribed if you think it is needed. There may be a small amount of bleeding which would present no health risk. There is a slight possibility of infection. Sterile techniques are used to avoid infection, but antibiotics can be used to treat an infection if this occurs. There is a very slight risk of temporary nerve damage, which should begin to heal within a few days. There should be no risk from answering any of the study questions, or in providing a urine sample.

Sometimes people find a question on a questionnaire sensitive or uncomfortable to answer. While there are reasons why the question is asked, you do not have to answer a particular question if you feel uncomfortable to do so. Please remember, all results will remain confidential. When we do the statistical analyses for the entire study we will not reveal your identity or the identity of anyone else in the study.

Adverse or allergic reactions to the foods promoted by the dietary intervention are rare. Occasionally, individuals have reported that consumption of the intervention foods leads to excess gas or diarrhea. We will ensure that you are in weekly contact with the project nutritionist and other research staff, and we will encourage you to call if you suspect any side effects. If any side effects occur, you may be advised to eat fewer of the vegetables.

Incorporation of a few additional foods to the diet may at times be an inconvenience when dining out or visiting people. There also may be inconvenience when planning or preparing meals for others in your home. The intervention class content and project staff will try to provide as much help as reasonably possible to overcome such inconveniences and to make these changes enjoyable. Through discussion and conversation, other classmates also may be able to help with these issues.

COMPENSATION IN CASE OF INJURY:

06-16-2000-06-15-2001

| Subject's | Initials | Witness's | Initials |
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All forms of medical diagnosis, treatment and research, whether routine or experimental, involve some risk of injury. In spite of all precautions, you might develop complications from participation in this study. In the event of any injury resulting directly from the research procedures, neither the study personnel, the University of South Carolina, nor the Palmetto Health Alliance have made any provision for the payment of any financial compensation to you or to provide any financial assistance for medical or other costs.

This study is being funded by the Department of Defense and conducted by the United States Army in conjunction with the University of South Carolina. Army regulations provide that, as a volunteer in a study conducted by the United States Army, you are authorized all necessary medical care for any injury or disease that is a direct result of your participation in the research. The Principal Investigator or his designee will assist you in obtaining appropriate medical treatment under this provision, if it is required. If you have any questions concerning your eligibility for Army-funded medical treatment you should discuss this issue thoroughly with the Principal Investigator or his designee before you enroll in this study. This is not a waiver or release of your legal rights.

BENEFITS:

This study may be of no direct benefit to you. However, we will make study results available to you when the final results are compiled and written. At the end of the study, you may request a summary of all of your own results with a brief description of what they mean. As results from the entire study are published, we will advise you and you may request them as well. Additionally, the knowledge gained from your participation in this research may help to better understand how to prevent or treat breast cancer.

COSTS:

There will be no direct cost to you for participating in the study. The analyses of questionnaires, blood, urine, biopsy material, and the dietary intervention classes will be provided free of charge.

If you are assigned to the dietary intervention, you will receive a supply of vegetables during each class that can be incorporated into the regular diet. This is done as a convenience to you, and the amount of vegetables supplied should be more than enough to meet the intervention objectives. However, such supplies are intended to be eaten by the study participant, and there will not be a sufficient quantity to share with others. In the event that you wish to share the provided vegetables with friends or family members, we would ask that you purchase additional vegetables.

REMOVAL FROM STUDY

You may be taken out of the research study if it appears that you are unable to: keep your appointments, provide blood, urine, a biopsy sample, or do not provide answers on the questionnaires. If this occurs, you will be given a full explanation.

CONFIDENTIALITY:

IRB APPROVAL

06-16-2000-06-15-2001

| Subject's | Initials | Witness's | Initials |
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Page 5 of 6

Your research records will be confidential. In all records of the study you will be identified by a code number and your name will be known only to the researchers. Your name will not be used in any reports or publications of this study.

Because this study is funded by the United States Department of Defense it has a special set of requirements known as "Volunteer Registry Data Base Requirements". It is the policy of the U.S. Army Medical Research and Materiel Command, the entity that regulates this research, that data sheets are to be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Data Base. The information to be entered into this confidential database includes your name, address, Social Security number, study name and dates. The intent of the database is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years. It should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

SAMPLE DONATION:

During this study, you will be asked to provide a breast biopsy sample and a urine sample. These samples will be used for hormone analysis related to breast cancer research. They also may be used for purposes that are currently unknown. There is a chance that the samples that you are donating under this study may be used in other research studies and may have some commercial value. No commercial value is anticipated at this point. Should your donated sample(s) lead to the development of a commercial product, the University of South Carolina will own it and may take action to patent and license the product. The University of South Carolina does not intend to provide you with any compensation for your participation in this study nor for any future value that the sample you have given may be found to have. You will not receive any notice of future uses of your sample(s).

PATIENT PROTECTION:

Further information on the research to be performed, or on any risks, benefits or alternative treatments may be obtained from James R. Hebert at 803-777-7666. This study has been approved by the committee to protect human rights for the Palmetto Health Alliance. Information concerning your rights as a research subject can be obtained by contacting the Office of Corporate Counsel at (803) 296-2124.

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| | | T | |
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| Witness' | 5 | initials | |
| | | | |
| | | | - |

Consent to Participate in the research project IRB #2000-78, entitled:

Phase I Induction and Estrogen Metabolism in Women With and Without Breast Cancer and in Response to a Dietary Intervention

| Subject's name: (printed or typewritten) | |
|--|--|
| P.I. Name: <u>James R. Hebert, Sc.D</u> | • |
| , ; | · |
| - | |
| | |
| "The purpose and procedures of this research | h project and the predictable discomfort, risks, and |
| - | to me. I have been told that unforeseen events may |
| | his with the investigator and all of my questions have |
| | unteer in this research project. I understand that I may nd that there is a possibility that the blood, tissue, or |
| | is study, may also be used in other research studies and |
| could potentially have some commercial appli | cability. I have been given a copy of this consent form. |
| 4 | |
| Person Obtaining Consent: | |
| | |
| Subject's signature: | Date: |
| 0.11 41 | |
| Subject's permanent address: | |
| | |
| **** | Data |
| Witness signature: | Date: |
| | |
| Witness' name (printed or typewritten) | Relationship to subject |

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| Subject's Initials | Witness's Initials |
|--------------------|--------------------|
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Palmetto Health Alliance

Biopsy Procedure Addendum IRB#: 2000-78

| Cancer and | uction and Estrogen Metabolism in Wome in Response to a Dietary Intervention | en With and Without Breast |
|---|--|--|
| Subject's nam | e: (printed or typewritten) | |
| P. I. Name: | James R. Hebert, Sc.D. | |
| | *************************************** | |
| RISKS AND | INCONVENIENCES: | |
| A fine-needle procedure use vein. | biopsy is used to collect tissue from under the sld to collect blood from a vein. However, it does | kin. It is very similar to the not require that the needle enter a |
| less than 12 he taken to reliev may be a smal possibility of to treat an infe | pain associated with the fine needle biopsy. The ours), and well tolerated. Pain medication, for extending the this pain, and Tylenol capsules will be available amount of bleeding which would present no he infection. Sterile techniques are used to avoid in extion, if this occurs. There is a very slight risk of the within several days. | example Tylenol or Advil, can be le at the time of the biopsy. There exalth risk. There is a slight fection, but antibiotics can be used |
| and benefits to events may of my questions project. I und is a possibility study, may al | e and procedures of this research project and that might result have been explained to me. It can. I have had an opportunity to discuss this have been answered. I agree to participate as derstand that I may end my participation at a total the blood, tissue, or urine samples, which is one used in other research studies and could pplicability. I have been given a copy of this of the can be used in the can be us | I have been told that unforeseen s with the investigator and all of a volunteer in this research ny time. I understand that there th I am providing under this potentially have some |
| Person Obtain | ning Consent: | |
| Subject's sign | ature: | Date: |
| Subject's per | manent address: | |
| Witness signa | ture: | Date: |
| Witness' nam | e (printed or typewritten) | Relationship to subject |

IRB APPROVAL

Palmetto Health Alliance Sample Donation Form IRB # 2000-78

TITLE: Phase I Induction and Estrogen Metabolism in Women With and Without Breast Cancer and in Response to a Dietary Intervention.

PRINCIPAL INVESTIGATOR: James R. Hebert, Sc.D.

| SUBJECT'S NAME: | DATE: |
|--|--|
| SPONSOR: <u>United States Department of Defense</u> | |
| SAMPLE DONATION: | |
| Occasionally, samples from one study are used in other studies. Usual progresses so that we can answer an important question that arises after therefore we did not anticipate. We will store samples of your blood, a part of this research for such a possible future use. For this reason, we statement: | er the study was begun, and breast tissue, and urine collected as |
| As a participant in <i>Phase I Induction and Estrogen Metabolism in Wo Cancer and in Response to a Dietary Intervention</i> , I voluntarily donat biopsy samples to the University of South Carolina. These samples we estrogens and proteins linked with estrogen degradation and may also Carolina for uses not currently known to me. There is a possibility the under this study may be used in other research studies and may have so commercial application is anticipated at this time. Should my donated of a commercial product, the University of South Carolina will own it patented and licensed by the University of South Carolina. The University of the University of South Carolina will not give me a sample(s). | te any and all urine, blood, and will be used for measurement of be used by the University of South at the samples that I am donating some commercial value. No d sample(s) lead to the development and it is possible that it will be the ersity of South Carolina does not |
| Person Obtaining Consent: | |
| Subject's signature: | Date: |
| Subject's permanent address: | |
| Witness' signature: | Date: |
| Witness' name (printed or typewritten) | Relationship to subject |

IRB APPROVAL

06-16-2000 - 06-15-2001

| DIRE | CT: Eligibility Questions Interviewer Name: |
|--------|--|
| | ct's Name: |
| | f contact: |
| Ромоон | n is incligible if response is DOLD |
| Person | n is ineligible if response is BOLD |
| Person | nal Characteristics: |
| Y N | Are you over 45 years of age? |
| Y N | Are you completely past menopause or past the change of life? |
| Y N | Do you plan to live in the Columbia, SC for the next six months? |
| ΥN | Do you smoke cigarettes or use any other tobacco product. |
| | How much do you weigh? |
| | How tall are you? (calculate BMI) |
| ΥN | |
| ΥN | BMI > 30 |
| Diet: | |
| YN | Are you on any diet or program to reduce or control your weight? |
| ΥN | Are you on any special diet for health reasons, such as a low salt diet or a low |
| | sugar diet? |
| YN | Are you using any nutritional supplements, other than vitamins? |
| YN | Do you consume more than 2 alcoholic drinks per day? |
| Medic | ation Use: |
| YN | Do you take any hormone replacement therapy? |
| | If Y, what type of therapy |
| | Y N Estrace or related brand |
| ΥN | Are you on any thyroid medication, antibiotics, diuretics, or steroids? |
| ΥN | Are you on any over-the-counter hormones (melatonin, black cohosh, see list)? |
| ΥN | Do you regularly take Tagamet for heart burn, for example? |
| Health | ı History: |
| YN | Have you been diagnosed with any type of cancer or malignancy in the past 5 |
| years | (non-cases only, excluding superficial skin lesions). |
| ΥN | Have you ever had a kidney or adrenal gland removed? |
| ΥN | Have you ever been told that you are diabetic? |
| ΥN | Have you ever been diagnosed with a liver disease, such as cirrhoses. |
| YN | Within the past year, have you been admitted to a psychiatric hospital? |
| Subjec | ctive assessment of interviewer: |
| | Will you provide a urine sample, blood sample, and a fine needle biopsy sample |
| YN | English sufficient to understand questions and provide quality data? |

Likely to complete study protocol as described in Consent Form?

Y N



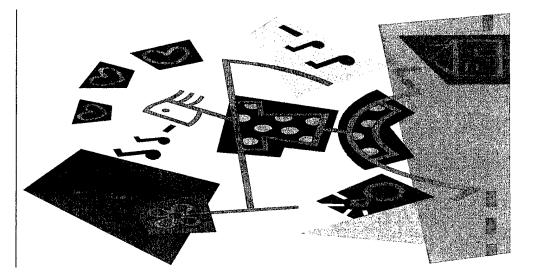
This research study is being conducted through the South Carolina Comprehensive Breast Center and the University of South Carolina School of Public Health.

The goal of the study is to evaluate the effect of a 4week dietary program on quality of life, body composition, and estrogen metabolism in postmenopausal women that have recently been received breast screening or who have been treated for breast cancer.



School of Public Health
Depts. of Epidemiology & Biostatistics
and Exercise Science
Columbia, SC 29208
803.777.9905





WHO IS ELIGIBLE?

You may be eligible to participate in this study if:

- you have had a biopsy intended to detected breast cancer in the last 2 months,
- you are postmenopausal,
- you do not smoke cigarettes.

WHAT WILL I BE ASKED TO DO?

You will be asked to:

- attend three dietary classes at the University of South Carolina, Columbia, SC
- Provide samples necessary to measure estrogen levels
- complete questionnaires and have your body composition measured,
- report your diet in a log and during interviewed with a dietician.

WHAT WILL I RECEIVE?

You will receive:

- a personalized dietary program (at no charge)
- a pedometer (step counter) to measure walking progress (\$20 value), and
- your personal study results.

Our project manager will call you in the next few days to answer any questions you may have.

Call 803.434.1628

Principal Investigators: James R. Hebert, Sc.D. Army Award: DAMD17-99-1-9279

Appendix 3
Collection & Processing

We are excited that you have agreed to participate in the Breast Health Study. Your help on this project will help us understand the best ways to improve the emotional and physical health of women with breast cancer.

Your clinic appointment is scheduled for <day, day, month> at <time>

We have included a map and directions to the site of your clinic appointment [South Carolina Cancer Center, Division of Population Studies, suite 301 in Richland Medical Park building 15 (next door to the CVS Pharmacy at the corner of Harden and Bull Streets)].

We have included a number of items in this packet. Please review the materials carefully;

- Fill out the questionnaires and bring them with you to your clinic appointment.
- Carefully follow the urine collection instructions, so that we can ensure all participants follow the same procedures.
 - We would like for you to collect samples from your first urine of the day (i.e., right after you get out of bed for the day).
 - O We would like for you to be "fasted" before each urine collection, so please do not eat food in the 8 hours before you collect the samples. For example, if you usually get out of bed a 7 AM, you should not eat anything after 11 PM the night before. You may drink fluids.
 - o Both urine collection containers have ascorbic acid in them as a preservative. Please do not pour the powder out of the containers.

If you have questions about what we would like you to do, please call Jay Fowke at 434-1628.

Directions to the South Carolina Cancer Center's Division of Population Studies

The site of your clinic appointment is at the Richland Memorial Hospital (RMH) Campus, in Richland Medical Park building 15, suite 301.

Richland Medical Park building 15 is located at 3555 Harden Street extension, and is right next door to the CVS Pharmacy at the corner of Harden Street and Bull Street, (near Highway 277).

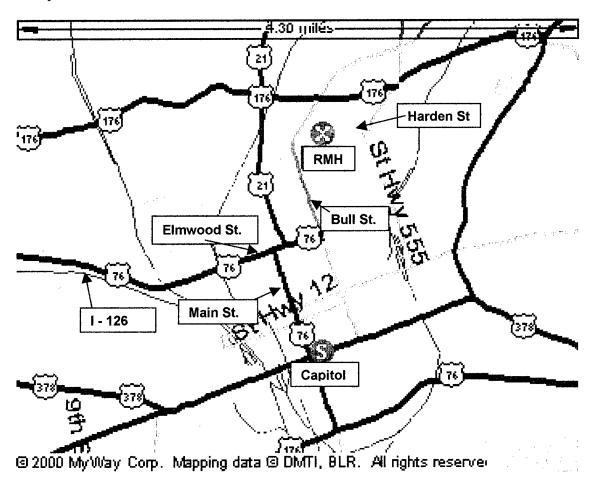
There is free-parking in front of Richland Medical Park building 15.

Enter the building through the front door, the elevators will be directly in front of you.

| - 184 | D | 7\\$faccuramanta\l fring | | ٠. |
|--------|----------------------|--|--------|--------|
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Once you arrive at the third floor, turn right out of the elevators, and follow the hallway to the entrance of suite 301, Division of Population Studies. There is a waiting area just inside the entrance.

The map below provides directions from the state Capitol to Richland Memorial Hospital (RMH) Campus.



| On | the DAY OF | vour | clinic | appointment | (|
|----------|---------------|------|--------|-------------|---|
| • | UIIU DILLI OX | | | appointment | / |

- (1) Collect the urine sample as soon as you get out of bed for the day.
 - o Use the "start stop -- collect" method to obtain the sample.
 - o If possible, fill the container at least half-full.
- (2) Refrain from eating for at least 8 hours before you obtain the sample.
- (3) Record the time you obtained the sample on the container's label.
- (4) Seal the jar tightly, place the container in the brown paper bag, and then put the bag in your refrigerator or freezer.
- (6) REMEMBER TO BRING BOTH OF YOUR <u>URINE SAMPLES</u> AND YOUR <u>QUESTIONNAIRES</u> TO YOUR CLINIC APPOINTMENT.

If you have questions about what we would like you to do, please call *** at ***.

We look forward to seeing you soon!

Urine Processing

- Participant delivers urine sample(s) to clinic in paper bag.
- Record the time and date of the sample on the clinic visit tracking form.
- Note any unusual characteristics of the sample (i.e., blood, odor, color) on visit tracking form.
- Check container lid for tightness.
- Mix sample container by inverting it 10 times.
- Using a transfer pipette, <u>fill 6 labeled cryovials for each sample</u> obtained. <u>Fill</u> each cryovial at least 75% full but no more (i.e., 1.5 mL).
- Tightly replace lids on cryovials.
- Place samples in the appropriate <u>shipment</u> and <u>storage</u> boxes, and place boxes in the -80° F freezer.
- Flush remaining urine.

Blood Processing

- Two (2) vacutainers of blood are collected from each subject
 - O Blood drawn from arm, using standard sterile procedures
 - o 1 red topped tube without anticoagulants

 - 1 lavender topped tube with EDTA
 The blood will be centrifuged at 3000 g for 15 minutes
 Plasma or serum will be removed

 - O Stored as five x 1 ml aliquots at -70 °C in labeled cryo-vials.
- Labels:
 - o ID
 - \circ \overline{S} if serum

 - P if plasmaB for Baseline
 - o F for Follow-up
 - o Example: 43PF

Buccal Cell collection

Buccal cells will be collected using the rinse and spit method

- O Rinse mouth with commercial mouth wash to clean mouth
- o Discard this wash
- o Rub sterile swab in mouth to loosen cells
- O Rinse mouth with sterile saline for 10 seconds, vigorously
- O Spit into specimen collection cup labeled with id and date
- o Provide towel to participant
- o Refrigerate sample until processed

Buccal Cell Sample Processing Protocol

Once the buccal cell samples have been received, follow the processing procedures outlined below:

- 1. Using a like vial marked with gradations, estimate and record the original sample volume on the Specimen Receipt Log.
- 2. Mix specimen thoroughly by gently inverting the wide mouth collection cup 4-6 times.
- 3. Using a 10mL pipet, transfer the specimen into a 15mL conical tube.
- 4. Centrifuge the specimen at 1500 x g (2730 rpm) for 15 minutes.
- 5. Using a 5 mL pipet, aliquot 1.8 mL of supernatant into each of the two prelabeled 2 mL vials, store them at -70° C, and discard the remaining supernatant by decantation.
- 6. Break the buccal cell pellet by gently tapping the 15 mL tube.
- 7. Resuspend the buccal cell pellet with 3.0 mL of TE buffer. Prepare TE buffer by adding 1.0 mL of TrisEDTA (100X) to 99.0 mL depc water. Store excess TE buffer at ambient temperature.
- 8. Using a 5 mL pipet, aliquot equal amounts of specimen into two 1.8 mL sterile cryovials.
- 9. Enter the default sample volume of 1.8 mL into the database for each vial.

 Record any processing problems in the Specimen Receipt Log and enter into database as appropriate.
- 10. Place the cryovials in a -70° C freezer for long-term storage.

DIRECT: Clinical and Anthropometric Data

| Participant ID: |
|---|
| Name: |
| Baseline Appointment Date:/ Time: AM PM Phlebotomist Code: ### |
| Weight:lbs Height:ftinches |
| Waist: inches Hips:inches |
| Blood: Y N Buccal: Y N Urine: Y N Fasting Y N Smoked (2 hrs): Y N Questionnaire Review: Y N Comments: |
| Postintervention Appointment Date:/ Time: AM PM Phlebotomist Code: ### |
| Weight:kg Waist:cm Hips:cm |
| Blood: Y N |
| Buccal: Y N |
| Urine: Y N Fasting Y N Smoked (2 hrs): Y N |
| Questionnaire Review: Y N |
| Comments: |

Principal Investigators: James R. Hebert, Sc.D. Army Award: DAMD17-99-1-9279

Appendix 4
Intervention Materials

DIRECT Study: Class Schedule

Class 1

Goals

- Introductions
- Discussion: Describe major focus of study
- Explain study design, objective, and expectations

Events

- Introductions
- Distribute recipes and other written material
- Introduce study vegetables (snack time)
- Discussion: Overview of Brassica and Breast Cancer
- Diet Diaries

Take Home Messages

- Eat several servings a day of Brassica to reach study goals
- Do not changes other parts of the diet
- Record diet in diaries

Class 2

Goals

- Cooking practicum
- Discussion: Preparation of Brassica
- Summarize Diet Diary

Events

- Comments/Issues of Concern
- Describe active ingredient(s) in Brassica
- Cooking Practicum
- Preparation Techniques

Take Home Messages

- Continue to add Brassica to diet
- Record diet in diaries
- Plan for Pot-luck meal

Class 3

Goals

- Potluck dinner
- Discussion: Overall Health Effects of Brassica

Events

- Potluck dinner B,K
- Discussion: Brassica and Health
- Distribute urine collection bottles and questionnaires

Take Home Messages

- Continue eating Brassica
- Focus on preparation methods
- Urine and blood collection week

Class 4

Goals

- Cooking practicum
- Guest speaker

Events

- Cooking practicum
- Guest speaker
- Study summary, discussion, and closing statements

Take Home Messages

- Continue with intervention diet, on your own, until blood drawn and urine collected
- Reminder that final urine/blood/24HR in about 3 weeks

Dietary Intervention to Reduce the Risk of Breast Cancer



FOOD DIARY

Name:

Dates of Diary:

1. Record everything you eat or drink in your Food Diary for 3 days. 2. Look up the number of points on last page of diary for each Brassic.

Look up the number of points on last page of diary for each Brassica serving, and record this number in the column labeled BRASSICA PTS.

3. Include comments about cooking and preparation for all Brassica foods.

Abbreviations: M/S = meal/snack, B=breakfast, L=lunch, S=snack, D=dinner

Day: Wednesday 4/1/98 (Brassica minimum goal = 10 points) F.X A MPI, F.

| LAF | EVANILLE | Day: Wednesday, $4/1/98$ (Brassica minimum goal = 10 points) | = 10 points) | |
|-----|----------|--|--------------|---------------------|
| M/S | Amount | Foods and Beverages | Brassica pts | Preparation/Cooking |
| В | | biscuit, 2" diameter | 0 | |
| | 1 tsp. | jam | 0 | |
| | 1 cup | coffee | 0 | |
| | 3 tsp. | whole milk | 0 | |
| | | | | |
| T | 1 | tuna sandwich | 0 | |
| | 1 cup | broccoli | 3 | chopped, raw |
| | 1 cup | cole slaw /white cabbage | 3 | chopped |
| | 12 oz | Coca-Cola | 0 | |
| | 1 oz | cheddar cheese | 0 | |
| | | | | |
| S | 1 | Brussels sprouts | 2 | steamed |
| | 8 oz | whole milk | 0 | |
| | | | | |
| D | 1 cup | beef stew, homemade | 0 | |
| | 1 cup | tossed salad, (lettuce, tomato, onion, cucumber) | 0 | |
| | 1/2 cup | savoy cabbage | 3.5 | chopped, raw |
| | 1 cup | iced tea | 0 | |
| | | | | |

Total Brassica 11.5

Look up the number of points for every serving of Brassica, and record this number in the column labeled BRASSICA PTS. 1. Record everything you eat or drink in your room Liany in June 2. Look up the number of points for every serving of Brassica, and record th 3. Include comments about cooking and preparation for all Brassica foods.

(Brassica minimum goal = 10 points) Day 1:

| Abbre | viations: $M/S = 1$ | Abbreviations: M/S = meal/snack, B=breakfast, L=lunch, S=snack, D=dinner | | |
|-------|---------------------|--|--------------|---------------------|
| M/S | Amount | Foods and Beverages | Brassica pts | Preparation/Cooking |
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| | | Total Brassica | | |

Record everything you eat or drink in your Food Diary for 3 days.

Look up the number of points for every serving of Brassica vegetable, and record this number in the column labeled BRASSICA. 1. Record everything you eat or drink in your roou Diany ion of ways.
2. Look up the number of points for every serving of Brassica vegetable, an
3. Include comments about cooking and preparation for all Brassica foods.

(Brassica minimum goal = 10 points) Day 2:

Preparation/Cooking Brassica pts Abbreviations: M/S = meal/snack, B=breakfast, L=lunch, S=snack, D=dinner Foods and Beverages Amount M/S

Total Brassica

Record everything you eat or drink in your Food Diary for 3 days.
 Look up the number of points for every serving of Brassica vegetable, and record this number in the column labeled BRASSICA.
 Include comments about cooking and preparation for all Brassica foods.

(Brassica minimum goal = 10 points) Day 3: _

| Abbreviations: N | Abbreviations: M/S = meal/snack, B=breakfast, L=lunch, S=snack, D=dinner | | |
|------------------|--|--------------|---------------------|
| M/S Amount | Foods and Beverages | Brassica pts | Preparation/Cooking |
| | | | |
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| | Total Brassica | | |

Find the vegetable and serving size that best fits what you ate.
 If you ate more or less Brassica in a serving than what is listed here, adjust and record the Brassica points accordingly.
 For example, ½ cup of chopped broccoli = 1.5 points. It is not necessary to be more precise.

Minimum Goal = 10 Points

| POINTS / SERVING | 2 | 7 | 5 | 4 | 3 | 3 | 3 | æ | 0 | | 3 | 2 | 3 | 2 | | 2 | | | 0 |
|------------------|------------------|---------------|----------------|-------|---------------|----------------|---------------|-----------------|------------|---------------|---------------|----------------|---------------|-----------------|-------------|---------|--------|---------|---------|
| Serving Size | 1 sprout | 1 cup chopped | 1 cup shredded | 1 cup | 1 cup chopped | 1 cup shredded | 1 cup chopped | 1 cup flowerets | 1 floweret | 1 cup chopped | 1 cup chopped | 1 cup shredded | 1 cup chopped | 1 cup flowerets | 1 cup-cubed | 1 large | 1 med | 1 small | 1 slice |
| Vegetable | Brussels Sprouts | Savoy Cabbage | Savoy Cabbage | Kale | Red Cabbage | Red Cabbage | Broccoli | Broccoli | Broccoli | Collards | White Cabbage | White Cabbage | Cauliflower | Cauliflower | Turnip | Turnip | Turnip | Turnip | Turnip |